

## **Bilag I**

**Liste over navne, lægemiddelforme, styrker ved lægemidlerne,  
administrationsmåder, indehavere af markedsføringstilladelsen i  
medlemslandene**

**Bilag IA: Lægemidler, for hvilke markedsføringstilladelserne anbefales opretholdt**

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                         | <b>Styrke</b> | <b>Lægemiddelform</b> | <b>Administrationsmåde</b> |
|--------------------------------|-----------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------------------|---------------|-----------------------|----------------------------|
| Østrig                         | Basics GmbH<br>Hemmelrather Weg 201<br>51377 Leverkusen<br>Germany          | Venlafaxin                              | Venlafaxin Ranbaxy<br>150 mg<br>Retardkapseln          | 150 mg        | Depotkapsel, hård     | Til oral anvendelse        |
| Østrig                         | Basics GmbH<br>Hemmelrather Weg 201<br>51377 Leverkusen<br>Germany          | Venlafaxin                              | Venlafaxin Ranbaxy<br>75 mg Retardkapseln              | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Østrig                         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlafaxin Bluefish 75mg<br>Hartkapseln retardiert     | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Østrig                         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlafaxin Bluefish<br>150mg Hartkapseln<br>retardiert | 150mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Østrig                         | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria               | Nebivolol                               | Nebilan 5mg Tabletten                                  | 5 mg          | Tablet                | Til oral anvendelse        |
| Østrig                         | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria               | Nebivolol                               | Nebivolol G.L. 5 mg -<br>Tabletten                     | 5 mg          | Tablet                | Til oral anvendelse        |

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|------------------------|-------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------|---------|---------------------------|---------------------|
| Østrig                 | ratiopharm Arzneimittel-<br>Vertriebs-GmbH<br>Albert-Schweitzer-Gasse 3<br>1140 Wien<br>Austria | Nebivolol                       | NEBIVOLOL-<br>RATIOPHARM 5 mg<br>Tabletten | 5 mg    | Tablet                    | Til oral anvendelse |
| Bulgarien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                     | Levetiracetam                   | Lyvam                                      | 250 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Bulgarien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                     | Levetiracetam                   | Lyvam                                      | 500 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Bulgarien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                     | Levetiracetam                   | Lyvam                                      | 750 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Bulgarien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                     | Levetiracetam                   | Lyvam                                      | 1000 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Bulgarien              | Ecopharm Group AD<br>bul. Cherni vrah 14, bl.3<br>Sofia 1421<br>Bulgaria                        | Nebivolol                       | Nevolen                                    | 5 mg    | Tablet                    | Til oral anvendelse |

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|--------------------------------|-------------------------------------------------------------------------------|-----------------------------------------|-----------------|---------------|---------------------------|----------------------------|
| Bulgarien                      | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia  | Fexofenadin                             | Ewofex          | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Bulgarien                      | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia  | Fexofenadin                             | Ewofex          | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Bulgarien                      | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol                               | Nebilan         | 5 mg          | Tablet                    | Til oral anvendelse        |
| Bulgarien                      | Neo Balkanika EOOD<br>35 Zemliane Str.<br>Sofia 1618<br>Bulgaria              | Nebivolol                               | Bivolet         | 5 mg          | Tablet                    | Til oral anvendelse        |
| Bulgarien                      | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                                | Bosentan Sandoz | 62,5 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Bulgarien                      | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                                | Bosentan Sandoz | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|---------------|---------------------------|----------------------------|
| Kroatien                       | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                                                                  | Levetiracetam                           | Lyvam 250 mg filmom<br>obložene tablete  | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Kroatien                       | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                                                                  | Levetiracetam                           | Lyvam 500 mg filmom<br>obložene tablete  | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Kroatien                       | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                                                                  | Levetiracetam                           | Lyvam 750 mg filmom<br>obložene tablete  | 750 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Kroatien                       | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                                                                  | Levetiracetam                           | Lyvam 1000 mg filmom<br>obložene tablete | 1000 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Cypern                         | Delorbis Pharmaceuticals Ltd<br>17 Athinon Street<br>Ergates Industrial Area<br>2643 Ergates<br>P.O. Box 28629<br>2081 Lefkosia<br>Cyprus | Levocetirizinhydrochlo<br>rid           | Zobral                                   | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|------------------------|---------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------|---------|---------------------------|---------------------|
| Tjekkiet               | Abdi Farma, Unipessoal Lda.<br>Quinta da Fonte, Rua dos<br>Malhoes<br>2770-071 Edificio D. Pedro I<br>Paco de Arcos<br>Portugal | Bosentanmonohydrat              | Bosentan Abdi 62,5 mg<br>potahované tablety      | 62,5 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Abdi Farma, Unipessoal Lda.<br>Quinta da Fonte, Rua dos<br>Malhoes<br>2770-071 Edificio D. Pedro I<br>Paco de Arcos<br>Portugal | Bosentanmonohydrat              | Bosentan Abdi 125 mg<br>potahované tablety       | 125 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Biofarm Sp. z o.o.<br>ul. Wałbrzyska 13<br>60-198 Poznań<br>Poland                                                              | Levocetirizinhydrochlorid       | Levocetirizin Biofarm<br>5 mg potahované tablety | 5 mg    | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                                     | Venlafaxin                      | Venlafaxine Bluefish<br>75 mg                    | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Tjekkiet               | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                                     | Venlafaxin                      | Venlafaxine Bluefish<br>150 mg                   | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |
| Tjekkiet               | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                                                    | Fexofenadinhydrochlorid         | Ewofex 120 mg<br>potahované tablety              | 120 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |

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|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------|---------|---------------------------|---------------------|
| Tjekkiet               | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                | Fexofenadinhydrochlorid         | Ewofex 180 mg<br>potahované tablety     | 180 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                   | Letiramyl 250 mg<br>potahované tablety  | 250 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                   | Letiramyl 500 mg<br>potahované tablety  | 500 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                   | Letiramyl 750 mg<br>potahované tablety  | 750 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                   | Letiramyl 1000 mg<br>potahované tablety | 1000 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Sandoz s.r.o.<br>U Nákladového nádraží 10<br>130 00 Prague 3<br>Czech Republic              | Bosentanmonohydrat              | Bosentan Sandoz<br>62,5 mg              | 62,5 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Tjekkiet               | Sandoz s.r.o.<br>U Nákladového nádraží 10<br>130 00 Prague 3<br>Czech Republic              | Bosentanmonohydrat              | Bosentan Sandoz 125 mg                  | 125 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |

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|--------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|---------------|---------------------------|----------------------------|
| Tjekkiet                       | Teva Pharmaceuticals CR, s.r.o.<br>Radlická 3185/1c<br>150 00 Prague 5<br>Czech Republic | Bosentanmonohydrat                      | Bosentan Teva 125 mg<br>potahované tablety | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany   | Levocetirizin                           | Levocetira                                 | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany   | Levocetirizin                           | Levcetin                                   | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Biofarm Sp. z o.o.<br>ul. Wałbrzyska 13<br>60-198 Poznań<br>Poland                       | Levocetirizin                           | Levrin                                     | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden              | Venlafaxinhydrochlorid                  | Venlafaxine Bluefish                       | 75 mg         | Depotkapsel               | Til oral anvendelse        |
| Danmark                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden              | Venlafaxinhydrochlorid                  | Venlafaxine Bluefish                       | 150 mg        | Depotkapsel               | Til oral anvendelse        |
| Danmark                        | Cipla Chanelle Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland       | Fexofenadin                             | Alterfast                                  | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|--------------------------------|------------------------------------------------------------------------------------|-----------------------------------------|----------------|---------------|---------------------------|----------------------------|
| Danmark                        | Cipla Chanelle Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Fexofenadin                             | Alterfast      | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Cipla Chanelle Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Fexofenadin                             | Clarifast      | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Cipla Chanelle Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Fexofenadin                             | Clarifast      | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Cipla Chanelle Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Fexofenadin                             | Histafast      | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Cipla Chanelle Generics Limited<br>Athenry Road,<br>Loughrea, Co Galway<br>Ireland | Fexofenadin                             | Histafast      | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                         | Fexofenadin                             | Nefoxef        | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                         | Fexofenadin                             | Nefoxef        | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------------------|---------------|---------------------------|----------------------------|
| Danmark                        | Norton Healthcare Ltd T/A Ivax<br>Pharmaceuticals UK<br>Ridings Point, Whistler Drive<br>Castleford<br>West Yorkshire WF10 5HX<br>United Kingdom | Fexofenadin                             | Fexofenadinhydrochlorid<br>"Ivax" | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Norton Healthcare Ltd T/A Ivax<br>Pharmaceuticals UK<br>Ridings Point, Whistler Drive<br>Castleford<br>West Yorkshire WF10 5HX<br>United Kingdom | Fexofenadin                             | Fexofenadinhydrochlorid<br>"Ivax" | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                                                                 | Metoclopramidhydroch<br>lorid           | Metoclopramide Orifarm            | 10 mg         | Tablet                    | Til oral anvendelse        |
| Danmark                        | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                                                                 | Fexofenadin                             | Altifex                           | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Danmark                        | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                                                                 | Fexofenadin                             | Altifex                           | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|--------------------------------|-------------------------------------------------------------------------------|-----------------------------------------|-------------------|---------------|---------------------------|----------------------------|
| Estland                        | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol                               | NEBITEN 5MG       | 5 mg          | Tablet                    | Til oral anvendelse        |
| Estland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaxin                              | VENLAFAXINE ORION | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Estland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaxin                              | VENLAFAXINE ORION | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Estland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaxin                              | VENLAFAXINE ORION | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Estland                        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                                | BOSENTAN SANDOZ   | 62,5 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Estland                        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                                | BOSENTAN SANDOZ   | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|--------------------------------|-------------------------------------------------------------------------------|-----------------------------------------|------------------------------|---------------|---------------------------|----------------------------|
| Estland                        | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                                | BOSENTAN NORAMEDA<br>62,5 mg | 62,5 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Estland                        | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                                | BOSENTAN NORAMEDA<br>125 mg  | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Estland                        | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                              | VENLAGAMMA 75 mg             | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Estland                        | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                              | VENLAGAMMA 150 mg            | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Finland                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid                  | Venlafaxine Bluefish         | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Finland                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid                  | Venlafaxine Bluefish         | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |

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|--------------------------------|----------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------------------|---------------|---------------------------|----------------------------|
| Finland                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                             | Fexofenadin                             | Nefoxef                                                | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Finland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland               | Venlafaxinhydrochlorid                  | VENLAFAXIN ORION                                       | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Finland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland               | Venlafaxinhydrochlorid                  | VENLAFAXIN ORION                                       | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Finland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland               | Venlafaxinhydrochlorid                  | VENLAFAXIN ORION                                       | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Frankrig                       | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany | Levocetirizin                           | Levocetira 5 mg<br>comprimé pelliculé                  | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Frankrig                       | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex                    | Fexofenadin                             | FEXOFENADINE<br>BIOGARAN 120 mg,<br>comprimé pelliculé | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

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|------------------------|------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------|---------|---------------------------|---------------------|
| Frankrig               | BIOGARAN<br>15, boulevard Charles de Gaulle<br>92707 Colombes Cedex    | Fexofenadin                     | FEXOFENADINE<br>BIOGARAN 180 mg,<br>comprimé pelliculé      | 180 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Fexofenadin                     | FEXOFENADINE MYLAN<br>120 Film-coated Tablet                | 120 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Fexofenadin                     | FEXOFENADINE MYLAN<br>180 Film-coated Tablet                | 180 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Levetiracetam                   | LEVETIRACETAM MYLAN<br>PHARMA 250mg,<br>comprimé pelliculé  | 250 mg  | Tablet                    | Til oral anvendelse |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Levetiracetam                   | LEVETIRACETAM MYLAN<br>PHARMA 500mg,<br>comprimé pelliculé  | 500 mg  | Tablet                    | Til oral anvendelse |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Levetiracetam                   | LEVETIRACETAM MYLAN<br>PHARMA 1000mg,<br>comprimé pelliculé | 1000 mg | Tablet                    | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                     | <b>Styrke</b> | <b>Lægemiddelform</b>      | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------------------------------|---------------|----------------------------|----------------------------|
| Frankrig                       | Plus Pharmacie SA<br>26 Boulevard Paul Vaillant-<br>Couturier<br>F-94200 Ivry-sur-Seine<br>France          | NEBIVOLOL                               | NEBIVOLOL ISOMED<br>5 mg, comprimé<br>quadrisécable                | 5 mg          | Tablet                     | Til oral anvendelse        |
| Frankrig                       | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Venlafaxin                              | Venlafaxine Ranbaxy LP<br>37,5mg, gélule à<br>libération prolongée | 37,5 mg       | Depotkapsel                | Til oral anvendelse        |
| Frankrig                       | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Venlafaxin                              | Venlafaxine Ranbaxy LP<br>75mg, gélule à libération<br>prolongée   | 75 mg         | Depotkapsel                | Til oral anvendelse        |
| Frankrig                       | Ranbaxy Pharmacie Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France                          | Venlafaxin                              | Venlafaxine Ranbaxy LP<br>150mg, gélule à<br>libération prolongée  | 150 mg        | Depotkapsel                | Til oral anvendelse        |
| Frankrig                       | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                                           | NEBIVOLOL                               | NEBIVOLOL RATIOPHARM<br>5 mg, comprimé<br>quadrisécable            | 5 mg          | Tablet                     | Til oral anvendelse        |
| Frankrig                       | Teva Sante<br>Cœur Défense - 100-110<br>Esplanade du Général de Gaulle<br>92931 La Défense Cedex<br>France | Fexofenadin                             | FEXOFENADINE TEVA<br>120 Film-coated Tablet                        | 120 mg        | Filmoverttrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                         | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
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| Frankrig                       | Teva Sante<br>Cœur Défense - 100-110<br>Esplanade du Général de Gaulle<br>92931 La Défense Cedex<br>France | Fexofenadin                             | FEXOFENADINE TEVA<br>180 Film-coated Tablet            | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Tyskland                       | AAA-Pharma GmbH<br>Liebknechtstrasse 33<br>70565 Stuttgart<br>Germany                                      | Venlafaxin                              | Venlafaxin AAA 75 mg<br>Hartkapseln, retardiert        | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Tyskland                       | AAA-Pharma GmbH<br>Liebknechtstrasse 33<br>70565 Stuttgart<br>Germany                                      | Venlafaxin                              | Venlafaxin AAA 150 mg<br>Hartkapseln, retardiert       | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Tyskland                       | AAA-Pharma GmbH<br>Liebknechtstrasse 33<br>70565 Stuttgart<br>Germany                                      | Venlafaxin                              | Venlafaxin AAA 37,5 mg<br>Hartkapseln, retardiert      | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Tyskland                       | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany                     | Levocetirizin                           | Levocetira 5 mg<br>Filmtabletten                       | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Tyskland                       | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaxin                              | Venlafaxin Bluefish<br>75 mg Hartkapsel,<br>retardiert | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                        | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                 | <b>Styrke</b> | <b>Lægemiddelform</b>      | <b>Administrationsmåde</b> |
|--------------------------------|----------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------|---------------|----------------------------|----------------------------|
| Tyskland                       | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                              | Venlafaxin                              | Venlafaxin Bluefish<br>150 mg Hartkapsel,<br>retardiert        | 15 mg         | Depotkapsel, hård          | Til oral anvendelse        |
| Tyskland                       | Dermapharm Aktiengesellschaft<br>Lil-Dagover-Ring 7<br>82031 Grünwald<br>Germany                         | Fexofenadin                             | Fexofenaderm 120 mg<br>Filmdabletten                           | 120 mg        | Filmovertrukken<br>tablett | Til oral anvendelse        |
| Tyskland                       | Dermapharm Aktiengesellschaft<br>Lil-Dagover-Ring 7<br>82031 Grünwald<br>Germany                         | Fexofenadin                             | Fexofenaderm 180mg<br>Filmdabletten                            | 180 mg        | Filmovertrukken<br>tablett | Til oral anvendelse        |
| Tyskland                       | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242<br>L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaxin                              | Venlafaxin Farmaprojects<br>37,5 mg Hartkapseln,<br>retardiert | 37,5 mg       | Depotkapsel, hård          | Til oral anvendelse        |
| Tyskland                       | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242<br>L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaxin                              | Venlafaxin Farmaprojects<br>75 mg Hartkapseln,<br>retardiert   | 75 mg         | Depotkapsel, hård          | Til oral anvendelse        |
| Tyskland                       | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242<br>L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaxin                              | Venlafaxin Farmaprojects<br>150 mg Hartkapseln,<br>retardiert  | 150 mg        | Depotkapsel, hård          | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                       | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                           | <b>Styrke</b> | <b>Lægemiddelform</b> | <b>Administrationsmåde</b> |
|--------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------|---------------|-----------------------|----------------------------|
| Tyskland                       | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                           | Nebivolol                               | NEBITEN 5MG                                              | 5 mg          | Tablet                | Til oral anvendelse        |
| Tyskland                       | Heumann Pharma GmbH & Co.<br>Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Venlafaxin                              | Venlafaxin Heumann<br>37,5 mg Hartkapseln,<br>retardiert | 37,5 mg       | Depotkapsel, hård     | Til oral anvendelse        |
| Tyskland                       | Heumann Pharma GmbH & Co.<br>Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Venlafaxin                              | Venlafaxin Heumann<br>75 mg Hartkapseln,<br>retardiert   | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Tyskland                       | Heumann Pharma GmbH & Co.<br>Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Venlafaxin                              | Venlafaxin Heumann<br>150 mg Hartkapseln,<br>retardiert  | 150 mg        | Depotkapsel, hård     | Til oral anvendelse        |
| Tyskland                       | Heumann Pharma GmbH & Co.<br>Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Nebivolol                               | Nebivolol Heumann 5 mg<br>Tabletten                      | 5 mg          | Tablet                | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                            | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                  | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|----------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------|---------------|---------------------------|----------------------------|
| Tyskland                       | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam                           | Levetiracetam-Hormosan<br>500 mg Filmtabletten  | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Tyskland                       | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam                           | Levetiracetam-Hormosan<br>750 mg Filmtabletten  | 750 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Tyskland                       | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam                           | Levetiracetam-Hormosan<br>1000 mg Filmtabletten | 1000 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Tyskland                       | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany | Levetiracetam                           | Levetiracetam-Hormosan<br>250 mg Filmtabletten  | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Tyskland                       | Lannacher Heilmittel<br>Ges.m.b.H.<br>Schlossplatz 1<br>8502 Lannach<br>Austria              | Nebivolol                               | Nebivolol Lannacher<br>5 mg Tabletten           | 5 mg          | Tablet                    | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                             | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                          | <b>Styrke</b> | <b>Lægemiddelform</b> | <b>Administrationsmåde</b> |
|--------------------------------|-------------------------------------------------------------------------------|-----------------------------------------|---------------------------------------------------------|---------------|-----------------------|----------------------------|
| Tyskland                       | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany              | Nebivolol                               | NEBIVOLOL-<br>RATIOPHARM 5mg                            | 5 mg          | Tablet                | Til oral anvendelse        |
| Tyskland                       | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany            | Nebivolol                               | Nebivolol Torrent 5 mg<br>Tabletten                     | 5 mg          | Tablet                | Til oral anvendelse        |
| Tyskland                       | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                              | Venlagamma retard<br>37.5 mg Hartkapseln,<br>retardiert | 37,5 mg       | Depotkapsel, hård     | Til oral anvendelse        |
| Tyskland                       | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                              | Venlagamma retard<br>75 mg Hartkapseln,<br>retardiert   | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Tyskland                       | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                              | Venlagamma retard<br>150 mg hartkapseln,<br>retardiert  | 150 mg        | Depotkapsel, hård     | Til oral anvendelse        |
| Grækenland                     | Pharmazac SA<br>31 Naoussis street<br>Athens 1447<br>Greece                   | Venlafaxin                              | Zacalen pr cap<br>75mg/cap                              | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                                       | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------------|--------|---------------------------|---------------------|
| Grækenland             | Pharmazac SA<br>31 Naoussis street<br>Athens 1447<br>Greece                                 | Venlafaxin                      | Zacalen pr cap<br>150mg/cap                                                   | 150 mg | Depotkapsel, hård         | Til oral anvendelse |
| Grækenland             | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                          | Nebivolol                       | Nebivolol Torrent 5 mg                                                        | 5 mg   | Tablet                    | Til oral anvendelse |
| Ungarn                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaxin                      | Venlafaxin Bluefish<br>150 mg nyújtott<br>hatóanyagleadású<br>kemény kapszula | 150 mg | Depotkapsel, hård         | Til oral anvendelse |
| Ungarn                 | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                | Fexofenadin                     | Ewofex 180 mg<br>filmtabletta                                                 | 180 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Ungarn                 | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Fexofenadin                     | Fexgen 120 mg<br>filmtabletta                                                 | 120 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Ungarn                 | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Fexofenadin                     | Fexgen 180 mg<br>filmtabletta                                                 | 180 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Ungarn                 | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                          | Nebivolol                       | Nebivolol Torrent 5 mg                                                        | 5 mg   | Tablet                    | Til oral anvendelse |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                     | Internationalt<br>generisk navn | Særnavn                                      | Styrke  | Lægemiddelform    | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|---------|-------------------|---------------------|
| Ungarn                 | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                      | Venlagamma 37,5 mg<br>retard kemény kapszula | 37,5 mg | Depotkapsel, hård | Til oral anvendelse |
| Ungarn                 | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                      | Venlagamma 75 mg<br>retard kemény kapszula   | 75 mg   | Depotkapsel, hård | Til oral anvendelse |
| Ungarn                 | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany | Venlafaxin                      | Venlagamma 150 mg<br>retard kemény kapszula  | 150 mg  | Depotkapsel, hård | Til oral anvendelse |
| Island                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid          | Venlafaxine Bluefish                         | 150 mg  | Depotkapsel, hård | Til oral anvendelse |
| Island                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid          | Venlafaxine Bluefish                         | 37,5 mg | Depotkapsel, hård | Til oral anvendelse |
| Island                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid          | Venlafaxine Bluefish                         | 75 mg   | Depotkapsel, hård | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                              | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-----------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Island                         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Fexofenadin                             | Nefoxef                                                     | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Island                         | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Fexofenadin                             | Nefoxef                                                     | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Irland                         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlablue XL 75 mg,<br>prolonged release<br>capsules, hard  | 75 mg         | Depotkapsel               | Til oral anvendelse        |
| Irland                         | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlablue XL 150 mg,<br>prolonged release<br>capsules, hard | 150 mg        | Depotkapsel               | Til oral anvendelse        |
| Irland                         | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland          | Fexofenadinhydrochlorid                 | Fexofenadine<br>hydrochloride 120 mg<br>Film-Coated tablets | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Irland                         | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland          | Fexofenadinhydrochlorid                 | Fexofenadine<br>hydrochloride 180 mg<br>Film-coated tablets | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                             | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                         | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------------------|---------------|---------------------------|----------------------------|
| Irland                         | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom | Venlafaxinhydrochlorid                  | Vensir XL 75 mg<br>prolonged-release hard<br>capsules  | 75 mg         | Depotkapsel               | Til oral anvendelse        |
| Irland                         | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom | Venlafaxinhydrochlorid                  | Vensir XL 150 mg<br>prolonged-release hard<br>capsules | 150 mg        | Depotkapsel               | Til oral anvendelse        |
| Italien                        | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany        | Levocetirizin                           | Levcetin 5 mg compresse<br>rivestite con film          | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Italien                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                   | Venlafaxin                              | VENLAFAXINA ABC                                        | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Italien                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                   | Venlafaxin                              | VENLAFAXINA ABC                                        | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Italien                        | Costanzafarma S.R.L.<br>Via Taranto, 4<br>20142 Milan<br>Italy                                | Fexofenadin                             | FIXODIN                                                | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Italien                        | Costanzafarma S.R.L.<br>Via Taranto, 4<br>20142 Milan<br>Italy                                | Fexofenadin                             | FIXODIN                                                | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                   | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                   | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
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| Italien                        | FB Health S.p.A.<br>Via dei Sabini, 28<br>63100 - Ascoli Piceno<br>Italy            | Venlafaxin                              | IXILANIA                         | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Italien                        | FB Health S.p.A.<br>Via dei Sabini, 28<br>63100 - Ascoli Piceno<br>Italy            | Venlafaxin                              | IXILANIA                         | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Italien                        | Germed Pharma S.P.A.<br>Via Cantu', 11<br>Cinisello Balsamo<br>Milan 20092<br>Italy | Nebivolol                               | NEBIVOLOLO GERMED                | 5 mg          | Tablet med<br>delekærv    | Til oral anvendelse        |
| Italien                        | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam                           | LEVETIRACETAM MYLAN<br>GENERICIS | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Italien                        | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam                           | LEVETIRACETAM MYLAN<br>GENERICIS | 750 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Italien                        | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                       | Levetiracetam                           | LEVETIRACETAM MYLAN<br>GENERICIS | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                  | Internationalt<br>generisk navn | Særnavn                        | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------|---------------------------------|--------------------------------|---------|---------------------------|---------------------|
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy              | Levetiracetam                   | LEVETIRACETAM MYLAN<br>GENERIC | 1000 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Italien                | MylanS.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy               | Fexofenadin                     | FEXOFENADINA MYLAN<br>GENERIC  | 120 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Italien                | MylanS.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy               | Fexofenadin                     | FEXOFENADINA MYLAN<br>GENERIC  | 180 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Italien                | Pensa Pharma S.P.A.<br>Via Rossellini Ippolito, 12<br>20124 Milan<br>Italy | Venlafaxin                      | VENLAFAXINA Pensa              | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Italien                | Pensa Pharma S.P.A.<br>Via Rossellini Ippolito, 12<br>20124 Milan<br>Italy | Venlafaxin                      | VENLAFAXINA Pensa              | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |
| Italien                | Progefarm S.r.l.<br>Largo Donegani 4/A<br>28100 - Novara<br>Italy          | Venlafaxin                      | VENLAFAXINA PROGE<br>FARM      | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Italien                | Progefarm S.r.l.<br>Largo Donegani 4/A<br>28100 - Novara<br>Italy          | Venlafaxin                      | VENLAFAXINA PROGE<br>FARM      | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                     | Internationalt<br>generisk navn | Særnavn                                                             | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------------------------|---------|---------------------------|---------------------|
| Italien                | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 - Milano<br>Italy | Venlafaxin                      | VENLAFAXINA RANBAXY<br>GENERICI                                     | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Italien                | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 - Milano<br>Italy | Venlafaxin                      | VENLAFAXINA RANBAXY<br>GENERICI                                     | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |
| Italien                | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 - Milano<br>Italy | Lansoprazol                     | Lansoprazolo<br>Ranbaxy 15 mg<br>capsule rigide<br>gastroresistenti | 15 mg   | Gastroresistent<br>tablet | Til oral anvendelse |
| Italien                | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 - Milano<br>Italy | Lansoprazol                     | Lansoprazolo<br>Ranbaxy 30 mg<br>capsule rigide<br>gastroresistenti | 30 mg   | Gastroresistent<br>tablet | Til oral anvendelse |
| Letland                | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                 | Nebivolol                       | Nebiten                                                             | 5 mg    | Tablet                    | Til oral anvendelse |
| Letland                | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaxin                      | Venlafaxine Orion                                                   | 37,5 mg | Depotkapsel, hård         | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                             | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                    | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-------------------------------------------------------------------------------|-----------------------------------------|---------------------------------------------------|---------------|---------------------------|----------------------------|
| Letland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland      | Venlafaxin                              | Venlafaxine Orion                                 | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Letland                        | Ranbaxy UK Ltd.<br>20 Balderton Street<br>London W1K 6TL<br>Untied Kingdom    | Lansoprazol                             | Lanobax 30 mg gastro-<br>resistant capsules, hard | 30 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |
| Letland                        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                                | Bosentan Sandoz                                   | 62,5 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Letland                        | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                                | Bosentan Sandoz                                   | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Letland                        | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                                | Bosentan Norameda                                 | 62,5 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Letland                        | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                                | Bosentan Norameda                                 | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>    | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------|---------------|---------------------------|----------------------------|
| Litauen                        | G.L. Pharma GmbH<br>Schlossplatz 1<br>8502 Lannach<br>Austria                                              | Nebivolol                               | Nebiten           | 5 mg          | Tablet                    | Til oral anvendelse        |
| Litauen                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                   | Venlafaxin                              | Venlafaxine Orion | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Litauen                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                   | Venlafaxin                              | Venlafaxine Orion | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Litauen                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                   | Venlafaxin                              | Venlafaxine Orion | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Litauen                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol                             | LANOBAX           | 30 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                     | Internationalt<br>generisk navn | Særnavn                | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------|---------------------------------|------------------------|---------|---------------------------|---------------------|
| Litauen                | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                        | Bosentan Sandoz        | 62,5 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Litauen                | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                        | Bosentan Sandoz        | 125 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany            | Nebivolol                       | Nebivolol Torrent 5 mg | 5 mg    | Tablet                    | Til oral anvendelse |
| Litauen                | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                        | Bosentan Norameda      | 62,5 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Litauen                | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                        | Bosentan Norameda      | 125 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Norge                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid          | Venlafaxin Bluefish    | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Norge                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden   | Venlafaxinhydrochlorid          | Venlafaxin Bluefish    | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn | Særnavn                 | Styrke | Lægemiddelform         | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|---------------------------------|-------------------------|--------|------------------------|---------------------|
| Norge                  | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Metoclopramidhydrochlorid       | Metoclopramide Orifarm  | 10 mg  | Tablet                 | Til oral anvendelse |
| Norge                  | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Fexofenadinhydrochlorid         | Altifex                 | 120 mg | Filmovertrukken tablet | Til oral anvendelse |
| Norge                  | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Fexofenadinhydrochlorid         | Altifex                 | 180 mg | Filmovertrukken tablet | Til oral anvendelse |
| Polen                  | Biofarm Sp. z o.o.<br>ul. Wałbrzyska 13<br>60-198 Poznań<br>Poland          | Levocetirizin                   | Zyx                     | 5 mg   | Filmovertrukken tablet | Til oral anvendelse |
| Polen                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxin                      | Venlafaxine Bluefish XL | 75 mg  | Depotkapsel, hård      | Til oral anvendelse |
| Polen                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxin                      | Venlafaxine Bluefish XL | 150 mg | Depotkapsel, hård      | Til oral anvendelse |
| Polen                  | Celon Pharma S.A.<br>Ogrodowa 2A, Kielpin<br>05-092 Łomianki,<br>Poland     | Bosentan                        | Bosentan Celon          | 125 mg | Filmovertrukken tablet | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>         | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------|------------------------|---------------|---------------------------|----------------------------|
| Polen                          | Farmaceutyczna Spółdzielnia<br>Pracy Galena<br>Krucza 62<br>50-984 Wrocław<br>Poland        | Fexofenadinhydrochlorid                 | Fexofast 120 mg        | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Farmaceutyczna Spółdzielnia<br>Pracy Galena<br>Krucza 62<br>50-984 Wrocław<br>Poland        | Fexofenadinhydrochlorid                 | Fexofast 180 mg        | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                           | Levetiracetam-Generics | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                           | Levetiracetam-Generics | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                           | Levetiracetam-Generics | 750 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Levetiracetam                           | Levetiracetam-Generics | 1000 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b> | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------|----------------|---------------|---------------------------|----------------------------|
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Fexofenadin                             | FexoGen        | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Fexofenadin                             | FexoGen        | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                    | Venlafaxin                              | Oriven         | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Polen                          | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                    | Venlafaxin                              | Oriven         | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Polen                          | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                    | Venlafaxin                              | Oriven         | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Polen                          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland                   | Lansoprazol                             | LANBAX         | 15 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                         | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>  | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------|-----------------------------------------|-----------------|---------------|---------------------------|----------------------------|
| Polen                          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland | Lansoprazol                             | LANBAX          | 30 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |
| Polen                          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland | Venlafaxin                              | Venlabax MR     | 37,5 mg       | Depotkapsel               | Til oral anvendelse        |
| Polen                          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland | Venlafaxin                              | Venlabax MR     | 75 mg         | Depotkapsel               | Til oral anvendelse        |
| Polen                          | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland | Venlafaxin                              | Venlabax MR     | 150 mg        | Depotkapsel               | Til oral anvendelse        |
| Polen                          | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria             | Bosentan                                | Bosentan Sandoz | 62,5 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Polen                          | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria             | Bosentan                                | Bosentan Sandoz | 125 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                    | Internationalt<br>generisk navn | Særnavn                 | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------|---------------------------------|-------------------------|---------|---------------------------|---------------------|
| Polen                  | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                | Venlafaxin                      | Venlagamma              | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Polen                  | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                | Venlafaxin                      | Venlagamma              | 37,5 mg | Depotkapsel, hård         | Til oral anvendelse |
| Polen                  | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany                | Venlafaxin                      | Venlagamma              | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |
| Polen                  | Zakłady Farmaceutyczne<br>POLPHARMA S.A. Pelplińska 19<br>83-200 Starogard Gdański<br>Poland | Fexofenadinhydrochlorid         | Telfexo 120 mg          | 120 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Polen                  | Zakłady Farmaceutyczne<br>POLPHARMA S.A. Pelplińska 19<br>83-200 Starogard Gdański<br>Poland | Fexofenadinhydrochlorid         | Telfexo 180 mg          | 180 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Portugal               | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                  | Venlafaxin                      | Venlafaxina Bluefish XR | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                          | Internationalt<br>generisk navn | Særnavn                 | Styrke  | Lægemiddelform    | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------|---------|-------------------|---------------------|
| Portugal               | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                                                        | Venlafaxin                      | Venlafaxina Bluefish XR | 150 mg  | Depotkapsel, hård | Til oral anvendelse |
| Portugal               | Bluepharma Genéricos -<br>Comércio de Medicamentos,<br>S.A.<br>São Martinho do Bispo<br>3045-016 Coimbra<br>Portugal                               | Venlafaxin                      | Venlafaxina Bluepharma  | 150 mg  | Depotkapsel, hård | Til oral anvendelse |
| Portugal               | Bluepharma Genéricos -<br>Comércio de Medicamentos,<br>S.A.<br>São Martinho do Bispo<br>3045-016 Coimbra<br>Portugal                               | Venlafaxin                      | Venlafaxina Bluepharma  | 75 mg   | Depotkapsel, hård | Til oral anvendelse |
| Portugal               | Bluepharma Genéricos -<br>Comércio de Medicamentos,<br>S.A.<br>São Martinho do Bispo<br>3045-016 Coimbra<br>Portugal                               | Venlafaxin                      | Venlafaxina Bluepharma  | 37,5 mg | Depotkapsel, hård | Til oral anvendelse |
| Portugal               | Eurogenus Farmacêutica,<br>Sociedade Unipessoal, Lda.<br>Rua Alto do Montijo, 13 - 2º<br>Dto., Edifício Monsanto<br>2790-012 Carnaxide<br>Portugal | Venlafaxin                      | Venlafaxina Eurogenus   | 37,5 mg | Depotkapsel, hård | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                                                  | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>        | <b>Styrke</b> | <b>Lægemiddelform</b>      | <b>Administrationsmåde</b> |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------|---------------|----------------------------|----------------------------|
| Portugal                       | Eurogenus Farmacêutica,<br>Sociedade Unipessoal, Lda.<br>Rua Alto do Montijo, 13 - 2º<br>Dto., Edifício Monsanto<br>2790-012 Carnaxide<br>Portugal | Venlafaxin                              | Venlafaxina Eurogenus | 75 mg         | Depotkapsel, hård          | Til oral anvendelse        |
| Portugal                       | Eurogenus Farmacêutica,<br>Sociedade Unipessoal, Lda.<br>Rua Alto do Montijo, 13 - 2º<br>Dto., Edifício Monsanto<br>2790-012 Carnaxide<br>Portugal | Venlafaxin                              | Venlafaxina Eurogenus | 150 mg        | Depotkapsel, hård          | Til oral anvendelse        |
| Portugal                       | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                | Nebivolol                               | Nebivolol Generis     | 5 mg          | tablet                     | Til oral anvendelse        |
| Portugal                       | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                | Nebivolol                               | Nebivolol Inventis    | 5 mg          | tablet                     | Til oral anvendelse        |
| Portugal                       | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                | Fexofenadin                             | Fexofenadina Generis  | 180 mg        | Filmoverttrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Sænavn</b>        | <b>Styrke</b> | <b>Lægemiddelform</b> | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------------|---------------|-----------------------|----------------------------|
| Portugal                       | Germed Farmacêutica, Lda.<br>Rua Alto do Montijo, 13 - 1º<br>Dto - Edifício Monsanto Portela<br>de Carnaxide<br>2790-012 Portela de Carnaxide<br>Portugal" | Nebivolol                               | Nebivolol Germed     | 5 mg          | Tablet                | Til oral anvendelse        |
| Portugal                       | GP - Genéricos Portugueses,<br>Lda.<br>Rua Henrique Paiva Couceiro,<br>29 - Venda Nova<br>2700-451 Amadora<br>Portugal                                     | Nebivolol                               | Nebivolol GP         | 5 mg          | tablet                | Til oral anvendelse        |
| Portugal                       | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, nº 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                      | Venlafaxinhydrochlorid                  | Venlafaxina Labesfal | 37,5 mg       | Depottablet           | til oral anvendelse        |
| Portugal                       | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, nº 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                      | Venlafaxinhydrochlorid                  | Venlafaxina Labesfal | 75 mg         | Depottablet           | til oral anvendelse        |
| Portugal                       | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, nº 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                      | Venlafaxinhydrochlorid                  | Venlafaxina Labesfal | 150 mg        | Depottablet           | til oral anvendelse        |
| Portugal                       | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, nº 1370<br>3465-051 Campo de Besteiros<br>Portugal                                                      | Nebivolol                               | Nebivolol Labesfal   | 5 mg          | tablet                | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                                                | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                      | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------|---------------|---------------------------|----------------------------|
| Portugal                       | Mylan, Lda.<br>Parque Expo, Edifício Atlantis,<br>Avenida D. João II, Lote<br>1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal              | Fexofenadin                             | Fexofenadina Mylan                  | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Portugal                       | Mylan, Lda.<br>Parque Expo, Edifício Atlantis,<br>Avenida D. João II, Lote<br>1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal              | Fexofenadin                             | Fexofenadina Mylan                  | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Portugal                       | Ratiopharm - Comércio e<br>Indústria de Produtos<br>Farmacêuticos, Lda.<br>Lagoas Park, Edifício 5 A, Piso 2<br>2740-245 Porto Salvo<br>Portugal | Nebivolol                               | Nebivolol Ratiopharm                | 5 mg          | Tablet                    | Til oral anvendelse        |
| Rumænien                       | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                                                                     | Fexofenadinhydrochlorid                 | Ewofex 120 mg<br>comprimate filmate | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Rumænien                       | Ewopharma International s.r.o.,<br>Hlavna 13<br>Bratislava 83101<br>Slovakia                                                                     | Fexofenadinhydrochlorid                 | Ewofex 180 mg<br>comprimate filmate | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                    | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Rumænien                       | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol                             | LEVANT                                                            | 15 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |
| Rumænien                       | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol                             | LEVANT                                                            | 30 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |
| Rumænien                       | Terapia SA<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                              | Venlafaxin                              | Venlafaxina Terapia<br>37.5 mg capsule cu<br>eliberare prelungită | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Rumænien                       | Terapia SA<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                              | Venlafaxin                              | Venlafaxina Terapia<br>75 mg capsule cu<br>eliberare prelungită   | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Rumænien                       | Terapia SA<br>Str. Fabricii nr. 124<br>Cluj Napoca<br>România                                              | Venlafaxin                              | Venlafaxina Terapia<br>150 mg capsule cu<br>eliberare prelungită  | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Rumænien                       | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania        | Nebivolol                               | Nebivolol Torrent com<br>primate                                  | 5 mg          | Tablet                    | Til oral anvendelse        |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                                     | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------------------|---------|---------------------------|---------------------|
| Rumænien               | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany               | Venlafaxin                      | Venlagamma 37,5 mg<br>capsule cu eliberare<br>prelungita                    | 37,5 mg | Depotkapsel, hård         | Til oral anvendelse |
| Rumænien               | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany               | Venlafaxin                      | Venlagamma 75 mg<br>capsule cu eliberare<br>prelungita                      | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Rumænien               | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany               | Venlafaxin                      | Venlagamma 150 mg<br>capsule cu eliberare<br>prelungita                     | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |
| Slovakiet              | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaxin                      | Venlafaxine Bluefish XR<br>75 mg tvrdé kapsuly s<br>predĺženým uvoľňovaním  | 75 mg   | Depotkapsel, hård         | Til oral anvendelse |
| Slovakiet              | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                 | Venlafaxin                      | Venlafaxine Bluefish XR<br>150 mg tvrdé kapsuly s<br>predĺženým uvoľňovaním | 150 mg  | Depotkapsel, hård         | Til oral anvendelse |
| Slovakiet              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Fexofenadin                     | Fexofenadin Generics<br>120 mg                                              | 120 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                           | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|---------------|---------------------------|----------------------------|
| Slovakiet                      | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Fexofenadin                             | Fexofenadin Generics<br>180 mg           | 160 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Slovakiet                      | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany               | Venlafaxin                              | Venlagamma 37,50 mg                      | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Slovakiet                      | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany               | Venlafaxin                              | Venlagamma 75 mg                         | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Slovakiet                      | Wörwag Pharma GmbH & Co.<br>KG<br>Calwer Str. 7<br>71034 Böblingen<br>Germany               | Venlafaxin                              | Venlagamma 150 mg                        | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Slovenien                      | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                 | Levetiracetam                           | Lyvam 250 mg filmsko<br>obložene tablete | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Slovenien                      | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                 | Levetiracetam                           | Lyvam 500 mg filmsko<br>obložene tablete | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                     | Internationalt<br>generisk navn | Særnavn                                                  | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------------|---------|---------------------------|---------------------|
| Slovenien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia   | Levetiracetam                   | Lyvam 750 mg filmsko<br>obložene tablete                 | 750 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Slovenien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia   | Levetiracetam                   | Lyvam 1000 mg filmsko<br>obložene tablete                | 1000 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Slovenien              | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                        | Bosentan Sandoz<br>62,5 mg filmsko obložene<br>tablete   | 62,5 mg | Filmovertrukken<br>tablet | Til oral anvendelse |
| Slovenien              | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia | Bosentan                        | Bosentan Sandoz 125 mg<br>filmsko obložene tablete       | 125 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Slovenien              | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                        | Bosentan Norameda<br>125 mg filmsko obložene<br>tablete  | 125 mg  | Filmovertrukken<br>tablet | Til oral anvendelse |
| Slovenien              | UAB Norameda<br>Meistru 8a<br>Vilnius LT-02189<br>Lithuania                   | Bosentan                        | Bosentan Norameda<br>62,5 mg filmsko obložene<br>tablete | 62,5 mg | Filmovertrukken<br>tablet | Til oral anvendelse |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                    | Internationalt<br>generisk navn | Særnavn                                                                                  | Styrke | Lægemiddelform    | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------------------------|--------|-------------------|---------------------|
| Spanien                | Aristo Pharma Iberia, S.L,<br>c/ Solana, 26, Torrejon de<br>Ardoz,<br>Madrid, 28850<br>Spain | Nebivolol                       | Nebivolol Edigen 5 mg<br>comprimidos efg                                                 | 5 mg   | Tablet            | Til oral anvendelse |
| Spanien                | Aristo Pharma Iberia, S.L,<br>c/ Solana, 26, Torrejon de<br>Ardoz,<br>Madrid, 28850<br>Spain | Venlafaxin                      | Venlafaxina Retard Urlabs<br>150 mg capsulas duras<br>de liberacion prolongada<br>efg    | 150 mg | Depotkapsel, hård | Til oral anvendelse |
| Spanien                | Aristo Pharma Iberia, S.L,<br>c/ Solana, 26, Torrejon de<br>Ardoz,<br>Madrid, 28850<br>Spain | Venlafaxin                      | Venlafaxina Retard Urlabs<br>75 mg capsulas duras de<br>liberacion prolongada efg        | 75 mg  | Depotkapsel, hård | Til oral anvendelse |
| Spanien                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                  | Venlafaxin                      | Venlafaxina Bluefish<br>150 mg capsulas de<br>liberacion prolongada efg                  | 150 mg | Depotkapsel       | Til oral anvendelse |
| Spanien                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                  | Venlafaxin                      | Venlafaxina Bluefish<br>75 mg capsulas de<br>liberacion prolongada efg                   | 75 mg  | Depotkapsel       | Til oral anvendelse |
| Spanien                | Laboratorios Ranbaxy, S. L U.<br>Paseig de Gracia 9<br>7a Pl<br>Barcelona 08007<br>Spain     | Venlafaxin                      | Venlafaxina Retard<br>Ranbaxygen 75 mg<br>capsulas duras de<br>liberacion prolongada efg | 75 mg  | Depotkapsel, hård | Til oral anvendelse |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                       | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                                             | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Spanien                        | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom                 | Levetiracetam                           | Levetiracetam Lupin<br>750 mg comprimidos<br>recubiertos con película<br>efg               | 750 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Spanien                        | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i Plegamans<br>(Barcelona)<br>Spain                 | Venlafaxin                              | Venlafaxina Retard<br>Pharmagenus 150 mg<br>capsulas duras de<br>liberacion prolongada efg | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Spanien                        | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i Plegamans<br>(Barcelona)<br>Spain                 | Venlafaxin                              | Venlafaxina Retard<br>Pharmagenus 75 mg<br>capsulas duras de<br>liberacion prolongada efg  | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Spanien                        | RATIOPHARM ESPAÑA, S.A.<br>C/ Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>28108 Alcobendas (Madrid)<br>Spain | Nebivolol                               | Nebivolol Ratio 5 mg<br>comprimidos efg                                                    | 5 mg          | Tablet                    | Til oral anvendelse        |
| Spanien                        | Teva Pharma S.L.U.<br>C/ Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>Madrid 28108<br>Spain                   | Fexofenadin                             | Fexofenadina Tevagen<br>120 mg comprimidos<br>recubiertos con película<br>efg              | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                     | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                                | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Spanien                        | Teva Pharma S.L.U.<br>C/ Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>Madrid 28108<br>Spain | Fexofenadin                             | Fexofenadina Tevagen<br>180 mg comprimidos<br>recubiertos con película<br>efg | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Spanien                        | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                   | Levetiracetam                           | Levetiracetam Lupin<br>1000 mg comprimidos<br>recubiertos con película<br>efg | 1000 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Spanien                        | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                   | Levetiracetam                           | Levetiracetam Lupin<br>250 mg comprimidos<br>recubiertos con película<br>efg  | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Spanien                        | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                   | Levetiracetam                           | Levetiracetam Lupin<br>500 mg comprimidos<br>recubiertos con película<br>efg  | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Sverige                        | Alternova A/S<br>Lodshusvej 11<br>DK-4230 Skælskør<br>Denmark                                         | Bendroflumethiazid                      | Bendroflumetiazid<br>Alternova                                                | 2,5 mg        | Tablet                    | Til oral anvendelse        |
| Sverige                        | Alternova A/S<br>Lodshusvej 11<br>DK-4230 Skælskør<br>Denmark                                         | Bendroflumethiazid                      | Bendroflumetiazid<br>Alternova                                                | 5 mg          | Tablet                    | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>         | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-----------------------------------------------------------------------------|-----------------------------------------|------------------------|---------------|---------------------------|----------------------------|
| Sverige                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlafaxin Bluefish    | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Sverige                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlafaxin Bluefish    | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Sverige                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Venlafaxinhydrochlorid                  | Venlafaxin Bluefish    | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Sverige                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Fexofenadin                             | Nefoxef                | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Sverige                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Fexofenadin                             | Nefoxef                | 160 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Sverige                        | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Metoclopramidhydroch<br>lorid           | Metoclopramide Orifarm | 10 mg         | Tablet                    | Til oral anvendelse        |
| Sverige                        | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark            | Fexofenadinhydrochlor<br>id             | Altifex                | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                             | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Sverige                        | Orifarm Generics A/S<br>PO BOX 69<br>DK-5260 Odense S<br>Denmark                                           | Fexofenadinhydrochlorid                 | Altifex                                                    | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Sverige                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Venlafaxin                              | Venlafaxin Ranbaxy<br>150 mg depotkapsel,<br>hård          | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Sverige                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Venlafaxin                              | Venlafaxin Ranbaxy<br>75 mg depotkapsel,<br>hård           | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Holland                        | Alfred E. Tiefenbacher GmbH<br>Van-der-Smissen-Strasse 1<br>D-22767 Hamburg<br>Germany                     | Levocetirizin                           | Levocetira 5 mg<br>filmomhulde tablet                      | 5 mg          | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Holland                        | Apothecon B.V.<br>Nijverheidsweg 3<br>3771 ME Barneveld<br>The Netherlands                                 | Fexofenadin                             | Fexofenadine HCL 120 A,<br>filmomhulde tabletten<br>120 mg | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Holland                        | Apothecon B.V.<br>Nijverheidsweg 3<br>3771 ME Barneveld<br>The Netherlands                                 | Fexofenadin                             | Fexofenadine HCL 180 A,<br>filmomhulde tabletten<br>120 mg | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                        | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                                   | <b>Styrke</b> | <b>Lægemiddelform</b> | <b>Administrationsmåde</b> |
|--------------------------------|----------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------------------------|---------------|-----------------------|----------------------------|
| Holland                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                              | Venlafaxin                              | Venlafaxine Bluefish<br>37,5 mg, capsules met<br>verlengde afgifte, hard         | 37,5 mg       | Depotkapsel, hård     | Til oral anvendelse        |
| Holland                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                              | Venlafaxin                              | Venlafaxine Bluefish<br>37,5 mg, capsules met<br>verlengde afgifte, hard         | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Holland                        | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                              | Venlafaxin                              | Venlafaxine Bluefish<br>37,5 mg, capsules met<br>verlengde afgifte, hard         | 150 mg        | Depotkapsel, hård     | Til oral anvendelse        |
| Holland                        | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242<br>L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaxin                              | Venlafaxine<br>Farmaprojects 37,5 mg,<br>capsules met verlengde<br>afgifte, hard | 37,5 mg       | Depotkapsel, hård     | Til oral anvendelse        |
| Holland                        | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242<br>L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaxin                              | Venlafaxine<br>Farmaprojects 75 mg,<br>capsules met verlengde<br>afgifte, hard   | 75 mg         | Depotkapsel, hård     | Til oral anvendelse        |
| Holland                        | Farmaprojects, S.A.U.<br>Santa Eulalia, 240-242<br>L'Hospitalet de Llobregat<br>08902 Barcelona<br>Spain | Venlafaxin                              | Venlafaxine<br>Farmaprojects 150 mg,<br>capsules met verlengde<br>afgifte, hard  | 150 mg        | Depotkapsel, hård     | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                 | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Holland                        | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Fexofenadin                             | Fexofenadine HCL Mylan<br>120 mg, filmomhulde<br>tabletten     | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Holland                        | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Fexofenadin                             | Fexofenadine HCL Mylan<br>180 mg, filmomhulde<br>tabletten     | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Holland                        | Pharmachemie B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                                      | Fexofenadin                             | Fexofenadine HCl 120<br>PCH, filmomhulde<br>tabletten 120 mg   | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Holland                        | Pharmachemie B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                                      | Fexofenadin                             | Fexofenadine HCl 180<br>PCH, filmomhulde<br>tabletten 120 mg   | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Holland                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol                             | Lansoprazol Ranbaxy<br>15 mg,<br>maagsapresistente<br>capsules | 15 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |
| Holland                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Lansoprazol                             | Lansoprazol Ranbaxy<br>30 mg,<br>maagsapresistente<br>capsules | 30 mg         | Gastroresistent<br>tablet | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                          | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                   | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Holland                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Venlafaxin                              | Venlafaxine Ranbaxy<br>75 mg, capsules met<br>verlengde afgifte  | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Holland                        | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>Untied Kingdom | Venlafaxin                              | Venlafaxine Ranbaxy<br>150 mg, capsules met<br>verlengde afgifte | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |
| Holland                        | ratiopharm Nederland B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                              | Fexofenadin                             | Fexofenadine HCl<br>ratiopharm 120 mg,<br>filmomhulde tabletten  | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Storbritannien                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaxinhydrochlorid                  | Venlablue XL 37.5mg<br>Prolonged Release<br>Capsules Hard        | 37,5 mg       | Depotkapsel, hård         | Til oral anvendelse        |
| Storbritannien                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaxinhydrochlorid                  | Venlablue XL 75mg<br>Prolonged Release<br>Capsules Hard          | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Storbritannien                 | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                | Venlafaxinhydrochlorid                  | Venlablue XL 150mg<br>Prolonged Release<br>Capsules Hard         | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                        | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                             | <b>Styrke</b> | <b>Lægemiddelform</b>            | <b>Administrationsmåde</b> |
|--------------------------------|----------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------------------------|---------------|----------------------------------|----------------------------|
| Storbritannien                 | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland                                       | Fexofenadin                             | Fexofenadine 120mg<br>film-coated tablets                  | 120 mg        | Filmovertrukken<br>tablet        | Til oral anvendelse        |
| Storbritannien                 | Chanelle Medical<br>Dublin road<br>Loughrea, Co. Galway<br>Ireland                                       | Fexofenadin                             | Fexofenadine 180mg<br>film-coated tablets                  | 180 mg        | Filmovertrukken<br>tablet        | Til oral anvendelse        |
| Storbritannien                 | Forum Products Limited<br>Crown House<br>2-8 Gloucester Road<br>Redhill Surrey RH1 1FH<br>United Kingdom | Venlafaxinhydrochlorid                  | Foraven XL 75mg<br>Modified Release<br>Capsules            | 75 mg         | Modificeret<br>depotkapsel, hård | Til oral anvendelse        |
| Storbritannien                 | Forum Products Limited<br>Crown House<br>2-8 Gloucester Road<br>Redhill Surrey RH1 1FH<br>United Kingdom | Venlafaxinhydrochlorid                  | Foraven XL 150mg<br>Modified Release<br>Capsules           | 150 mg        | Modificeret<br>depotkapsel, hård | Til oral anvendelse        |
| Storbritannien                 | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Fexofenadin                             | Fexofenadine<br>hydrochloride 120mg<br>Film-coated tablets | 120 mg        | Filmovertrukken<br>tablet        | Til oral anvendelse        |
| Storbritannien                 | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom              | Fexofenadin                             | Fexofenadine<br>hydrochloride 180mg<br>Film-coated tablets | 180 mg        | Filmovertrukken<br>tablet        | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                       | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                        | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------|---------------|---------------------------|----------------------------|
| Storbritannien                 | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam                           | Levetiracetam Lupin<br>250mg Film-coated<br>tablets   | 250 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Storbritannien                 | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam                           | Levetiracetam Lupin<br>500mg Film-coated<br>tablets   | 500 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Storbritannien                 | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam                           | Levetiracetam Lupin<br>750mg Film-coated<br>tablets   | 750 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Storbritannien                 | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16 0PF<br>United Kingdom | Levetiracetam                           | Levetiracetam Lupin<br>1000mg Film-coated<br>tablets  | 1000 mg       | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Storbritannien                 | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom           | Venlafaxinhydrochlorid                  | Vensir XL 75mg<br>Prolonged Release Hard<br>Capsules  | 75 mg         | Depotkapsel, hård         | Til oral anvendelse        |
| Storbritannien                 | Morningside Healthcare Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom           | Venlafaxinhydrochlorid                  | Vensir XL 150mg<br>Prolonged Release Hard<br>Capsules | 150 mg        | Depotkapsel, hård         | Til oral anvendelse        |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                     | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                            | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------|---------------|---------------------------|----------------------------|
| Storbritannien                 | Teva UK Limited<br>Brampton Road<br>Hampden Park<br>Sussex BN22 9AG<br>United Kingdom | Fexofenadin                             | Fexofenadine 120mg<br>film-coated tablets | 120 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |
| Storbritannien                 | Teva UK Limited<br>Brampton Road<br>Hampden Park<br>Sussex BN22 9AG<br>United Kingdom | Fexofenadin                             | Fexofenadine 180mg<br>film-coated tablets | 180 mg        | Filmovertrukken<br>tablet | Til oral anvendelse        |

**BILAG IB: Lægemidler, for hvilke markedsføringstilladelseerne anbefales suspenderet**

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                            | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                 | <b>Styrke</b> | <b>Lægemiddelform</b> | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------|---------------|-----------------------|----------------------------|
| Østrig                         | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Esomeprazolmagnesium                    | Esomeprazol Arcana 20<br>mg magensaftresistente<br>Hartkapseln | 20 mg         | Enterokapsel, hård    | Oral anvendelse            |
| Østrig                         | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Esomeprazolmagnesium                    | Esomeprazol Arcana 40<br>mg magensaftresistente<br>Hartkapseln | 40 mg         | Enterokapsel, hård    | Oral anvendelse            |
| Østrig                         | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Esomeprazolmagnesium                    | Neximyl 20 mg<br>magensaftresistente<br>Hartkapseln            | 20 mg         | Enterokapsel, hård    | Oral anvendelse            |
| Østrig                         | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Esomeprazolmagnesium                    | Neximyl 40 mg<br>magensaftresistente<br>Hartkapseln            | 40 mg         | Enterokapsel, hård    | Oral anvendelse            |
| Østrig                         | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Candesartancilexetil                    | Candesartan Arcana 4mg<br>Tabletten                            | 4 mg          | Tablet                | Oral anvendelse            |
| Østrig                         | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria | Candesartancilexetil                    | Candesartan Arcana 8mg<br>Tabletten                            | 8mg           | Tablet                | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                       | Internationalt<br>generisk navn | Særnavn                                            | Styrke | Lægemiddelform             | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------|--------|----------------------------|---------------------|
| Østrig                 | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                    | Candesartancilexetil            | Candesartan Arcana<br>16mg Tabletten               | 16 mg  | Tablet                     | Oral anvendelse     |
| Østrig                 | Arcana Arzneimittel GmbH<br>Huetteldorfer Straße 299<br>1140 Wien<br>Austria                    | Candesartancilexetil            | Candesartan Arcana<br>32mg Tabletten               | 32 mg  | Tablet                     | Oral anvendelse     |
| Østrig                 | Genericon Pharma GmbH<br>Hafnerstr. 211<br>8054 Graz<br>Austria                                 | Nebivolol                       | Nebivolol Genericon 5 mg<br>Tabletten              | 5 mg   | Tablet                     | Oral anvendelse     |
| Østrig                 | ratiopharm Arzneimittei-<br>Vertriebs-GmbH<br>Albert-Schweitzer-Gasse 3<br>1140 Wien<br>Austria | Desloratadin                    | Desloratadin ratiopharm<br>2,5 mg Schmelztabletten | 2,5 mg | Smeltetablet               | Oral anvendelse     |
| Østrig                 | ratiopharm Arzneimittei-<br>Vertriebs-GmbH<br>Albert-Schweitzer-Gasse 3<br>1140 Wien<br>Austria | Desloratadin                    | Desloratadin ratiopharm<br>5 mg Schmelztabletten   | 5 mg   | Smeltetablet               | Oral anvendelse     |
| Belgien                | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                          | Desloratadin                    | Desloratadine Apotex                               | 5 mg   | Filmoverttrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                            | Internationalt<br>generisk navn | Særnavn                            | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|----------------------------------------------------------------------|---------------------------------|------------------------------------|--------|----------------|---------------------|
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Donepezil                       | Donepezil Odis Mylan               | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Donepezil                       | Donepezil Odis Mylan               | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Repaglinid                      | Repaglinide Mylan 0,5 mg<br>Pharma | 0,5 mg | Tablet         | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Repaglinid                      | Repaglinide Mylan 1 mg<br>Pharma   | 1 mg   | Tablet         | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Repaglinid                      | Repaglinide Mylan 2mg<br>Pharma    | 2 mg   | Tablet         | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Candesartan                     | Candesartan Mylan                  | 8 mg   | Tablet         | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Candesartan                     | Candesartan Mylan                  | 16 mg  | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                            | Internationalt<br>generisk navn | Særnavn            | Styrke | Lægemiddelform     | Administrationsmåde |
|------------------------|----------------------------------------------------------------------|---------------------------------|--------------------|--------|--------------------|---------------------|
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Candesartan                     | Candesartan Mylan  | 32 mg  | Tablet             | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Esomeprazol                     | Esomeprazole Mylan | 20 mg  | Enterokapsel, hård | Oral anvendelse     |
| Belgien                | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Esomeprazol                     | Esomeprazole Mylan | 40 mg  | Enterokapsel, hård | Oral anvendelse     |
| Belgien                | Takeda Belgium<br>Gentsesteenweg 615<br>1080 Brussels<br>Belgium     | Alendroninsyre                  | Alendromono        | 70 mg  | Tablet             | Oral anvendelse     |
| Belgien                | Teva Pharma Belgium NV<br>Laarstraat 16<br>2610 Wilrijk<br>Belgium   | Desloratadin                    | Desloratadine Teva | 2,5 mg | Smeltetablet       | Oral anvendelse     |
| Belgien                | Teva Pharma Belgium NV<br>Laarstraat 16<br>2610 Wilrijk<br>Belgium   | Desloratadin                    | Desloratadine Teva | 5 mg   | Smeltetablet       | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn           | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------|--------|---------------------------|---------------------|
| Bulgarien              | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole Accord | 0,5 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole Accord | 1 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole Accord | 2 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole Accord | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                                        | Cefpodoxim                      | FOXERO            | 200 mg | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                   | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------|--------|---------------------------|---------------------|
| Bulgarien              | Aquachim AD<br>blvd. Prof. Tsvetan Lazarov<br>83<br>Sofia 1582<br>Bulgaria                  | Quetiapin                       | Aquatiapine                               | 25 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Aquachim AD<br>blvd. Prof. Tsvetan Lazarov<br>83<br>Sofia 1582<br>Bulgaria                  | Quetiapin                       | Aquatiapine                               | 100 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Aquachim AD<br>blvd. Prof. Tsvetan Lazarov<br>83<br>Sofia 1582<br>Bulgaria                  | Quetiapin                       | Aquatiapine                               | 200 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esopragen                                 | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Bulgarien              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esopragen                                 | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Bulgarien              | Glenmark Pharmaceuticals<br>s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic   | Trimetazidin                    | Apstar 35 mg<br>prolonged-release tablets | 35 mg  | Depottablet               | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                  | Internationalt<br>generisk navn | Særnavn                                          | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------|---------|---------------------------|---------------------|
| Bulgarien              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                     | Trimetazidin                    | Trimetazigen MR                                  | 35 mg   | Depottablet               | Oral anvendelse     |
| Bulgarien              | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia              | Trimetazidin                    | Energotrim                                       | 35 mg   | Depottablet               | Oral anvendelse     |
| Bulgarien              | Tchaikapharma Highquality<br>Medicines<br>1 G. M. Dimitrov Blvd.<br>Sofia 1172<br>Bulgaria | Bosentan                        | Pulmohyperta                                     | 62,5 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Bulgarien              | Tchaikapharma Highquality<br>Medicines<br>1 G. M. Dimitrov Blvd.<br>Sofia 1172<br>Bulgaria | Bosentan                        | Pulmohyperta                                     | 125 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Kroatien               | Alkaloid d.o.o.<br>Ulica grada Vukovara 226 F<br>Zagreb 10000<br>Croatia                   | Cefpodoxim                      | Rexocef 200 mg filmom<br>obložene tablete        | 200 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Kroatien               | Belupo, lijekovi i kozmetika<br>d.d.<br>Ulica Danica 5<br>Koprivnica 48000<br>Croatia      | Desloratadin                    | Alerdin 2,5 mg<br>raspadljive tablete za<br>usta | 2,5 mg  | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                             | Internationalt<br>generisk navn | Særnavn                                                                       | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Kroatien               | Belupo, lijekovi i kozmetika<br>d.d.<br>Ulica Danica 5<br>Koprivnica 48000<br>Croatia | Desloratadin                    | Alerdin 5 mg raspadljive<br>tablete za usta                                   | 5 mg              | Smeltetablet              | Oral anvendelse     |
| Kroatien               | Fidifarm d.o.o.<br>Obrtnička 37, Bestovje<br>Rakitje 10437<br>Croatia                 | Desloratadin                    | Sinalerg 5 mg filmom<br>obložene tablete                                      | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Kroatien               | Jadran Galenski Laboratorij<br>d.d.<br>Svilno 20, Rijeka<br>51000<br>Croatia          | Desloratadin                    | Escontral direkt 2,5 mg<br>raspadljiva tableta za<br>usta                     | 2,5 mg            | Smeltetablet              | Oral anvendelse     |
| Kroatien               | Jadran Galenski Laboratorij<br>d.d.<br>Svilno 20, Rijeka<br>51000<br>Croatia          | Desloratadin                    | Escontral direkt 5 mg<br>raspadljiva tableta za<br>usta                       | 5 mg              | Smeltetablet              | Oral anvendelse     |
| Kroatien               | PharmaS d.o.o.<br>Radnička cesta 47<br>Zagreb 10000<br>Croatia                        | Tramadol/paracetamol            | Tramadol/Paracetamol<br>PharmaS 37,5 mg/<br>325 mg filmom obložene<br>tablete | 37,5 mg/325<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Kroatien               | PharmaS d.o.o.<br>Radnička cesta 47<br>Zagreb 10000<br>Croatia                        | Escitalopram                    | Escitalopram PharmaS 10<br>mg filmom<br>obložene tablete                      | 10 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                 | Internationalt<br>generisk navn  | Særnavn                                                | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------------------------------------|-------------------|---------------------------|---------------------|
| Kroatien               | Sandoz d.o.o.<br>Maksimirska 120<br>Zagreb 10000<br>Croatia                                                                               | Trimetazidinhydrochlorid         | Vazidin 35 mg tablete s<br>produljenim<br>oslobađanjem | 35 mg             | Depottablet               | Oral anvendelse     |
| Cypern                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom                        | Alendroninsyre                   | Alendronic Acid Accord                                 | 70 mg             | Tablet                    | Oral anvendelse     |
| Cypern                 | Delorbis Pharmaceuticals Ltd<br>17 Athinon Street<br>Ergates Industrial Area<br>2643 Ergates<br>P.O. Box 28629<br>2081 Lefkosia<br>Cyprus | Entacapon                        | Nobat                                                  | 200 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Cypern                 | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                                               | Valsartan/hydrochlorothi<br>azid | Valsartan/Hctz Fair-med                                | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Cypern                 | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece                                          | Donepezilhydrochlorid            | Donepezil/Generics                                     | 5 mg              | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                           | Internationalt<br>generisk navn | Særnavn            | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------|---------|---------------------------|---------------------|
| Cypern                 | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece                    | Donepezilhydrochlorid           | Donepezil/Generics | 10 mg   | Smeltetablet              | Oral anvendelse     |
| Cypern                 | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirolhydrochlorid           | Ropinirole Lambda  | 0,25 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Cypern                 | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirolhydrochlorid           | Ropinirole Lambda  | 0,5 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Cypern                 | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirolhydrochlorid           | Ropinirole Lambda  | 1 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                   | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>        | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------|---------------|---------------------------|----------------------------|
| Cypern                         | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirolhydrochlorid                   | Ropinirole Lambda     | 2 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |
| Cypern                         | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirolhydrochlorid                   | Ropinirole Lambda     | 5 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |
| Cypern                         | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom           | Clopidogrelhydrochlorid                 | Clopidogrel/Wockhardt | 75 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |
| Tjekkiet                       | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 - Hadovka<br>Office Park<br>Czech Republic       | Escitalopramoxalat                      | Purcema 5 mg          | 5 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |
| Tjekkiet                       | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 - Hadovka<br>Office Park<br>Czech Republic       | Escitalopramoxalat                      | Purcema 10 mg         | 10 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                     | Internationalt<br>generisk navn | Særnavn                                         | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------|--------|---------------------------|---------------------|
| Tjekkiet               | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 - Hadovka<br>Office Park<br>Czech Republic | Escitalopramoxalat              | Purcema 15 mg                                   | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tjekkiet               | Abbott Laboratories, s.r.o.<br>Evropská 2591/33d<br>160 00 Praha 6 - Hadovka<br>Office Park<br>Czech Republic | Escitalopramoxalat              | Purcema 20 mg                                   | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tjekkiet               | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland                               | Metforminhydrochlorid           | Metformin Actavis Retard<br>500 mg              | 500 mg | Depottablet               | Oral anvendelse     |
| Tjekkiet               | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland                               | Metforminhydrochlorid           | Metformin Actavis Retard<br>750 mg              | 750 mg | Depottablet               | Oral anvendelse     |
| Tjekkiet               | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                                   | Cefpodoxim                      | Forexo 200 mg<br>potahované tablety             | 200 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tjekkiet               | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Luxembourg                                 | Desloratadin                    | Desloratadin Alvogen 5<br>mg potahované tablety | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                | Styrke | Lægemiddelform     | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------|--------|--------------------|---------------------|
| Tjekkiet               | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                      | Trimetazidindihydrochlorid      | Apo-trimetazidin 35 mg                                 | 35 mg  | Depottablet        | Oral anvendelse     |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomylan 40 mg                                         | 40 mg  | Enterokapsel, hård | Oral anvendelse     |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Rizatriptanbenzoat              | Rizatriptan Mylan 5 mg                                 | 5 mg   | Smeltetablet       | Oral anvendelse     |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Rizatriptanbenzoat              | Rizatriptan Mylan 10 mg                                | 10 mg  | Smeltetablet       | Oral anvendelse     |
| Tjekkiet               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezilhydrochlorid           | Donepezil Mylan 10 mg                                  | 10 mg  | Smeltetablet       | Oral anvendelse     |
| Tjekkiet               | Glenmark Pharmaceuticals<br>s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic   | Trimetazidindihydrochlorid      | Portora 35 mg tablety s<br>prodlouženým<br>uvolňováním | 35 mg  | Depottablet        | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                    | Internationalt<br>generisk navn | Særnavn                                                             | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------------------------|--------|---------------------------|---------------------|
| Tjekkiet               | GNR Czech s.r.o.<br>Slavojova 579/9<br>128 00 Praha 2<br>Czech Republic                      | Desloratadin                    | Geslora 5 mg                                                        | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tjekkiet               | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                   | Desloratadin                    | Desloratadin Labormed<br>2,5 mg tablety<br>dispergovatelne v ústech | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Tjekkiet               | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                   | Desloratadin                    | Desloratadin Labormed 5<br>mg tablety<br>dispergovatelne v ústech   | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Tjekkiet               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                       | Trimetazidin                    | Trimetazidin Mylan 35<br>mg                                         | 35 mg  | Depottablet               | Oral anvendelse     |
| Tjekkiet               | SVUS Pharma a.s.<br>Smetanovo nábřeží<br>1238/20a<br>500 02 Hradec Králové<br>Czech Republic | Desloratadin                    | Lotera 5 mg potahované<br>tablety                                   | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Danmark                | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland              | Metformin                       | Metformin "Actavis PTC"                                             | 500 mg | Depottablet               | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                       | Internationalt<br>generisk navn  | Særnavn                                    | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------|----------------------------------|--------------------------------------------|-------------------|---------------------------|---------------------|
| Danmark                | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformin                        | Metformin "Actavis PTC"                    | 750 mg            | Depottablet               | Oral anvendelse     |
| Danmark                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Fluconazol                       | Fluconazol "Bluefish"                      | 50 mg             | Kapsel, hård              | Oral anvendelse     |
| Danmark                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Fluconazol                       | Fluconazol "Bluefish"                      | 150 mg            | Kapsel, hård              | Oral anvendelse     |
| Danmark                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Fluconazol                       | Fluconazol "Bluefish"                      | 200 mg            | Kapsel, hård              | Oral anvendelse     |
| Danmark                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/hydrochlorothi<br>azid | Valsartan/hydrochlorthiaz<br>id "Fair-Med" | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Danmark                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/hydrochlorothi<br>azid | Valsartan/hydrochlorthiaz<br>id "Fair-Med" | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Danmark                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany     | Valsartan/hydrochlorothi<br>azid | Valsartan/hydrochlorthiaz<br>id "Fair-Med" | 320 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                        | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------|--------|---------------------------|---------------------|
| Danmark                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                         | Eletriptan                      | Eletriptan Mylan               | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Danmark                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                         | Esomeprazol                     | Esomeprazol Mylan              | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Danmark                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                         | Esomeprazol                     | Esomeprazol Mylan              | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Danmark                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                                         | Rizatriptan                     | Rizatriptan Mylan              | 10 mg  | Smeltetablet              | Oral anvendelse     |
| Danmark                | Stadapharm GmbH<br>Stadastr. 2-18<br>D-61118 Bad Vilbel<br>Germany                                                 | Entacapon                       | Entacapon STADA                | 200 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Estland                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | ALENDRONIC ACID<br>ACCORD 70MG | 70 mg  | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                       | Internationalt<br>generisk navn | Særnavn             | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------|---------------------------------|---------------------|--------|----------------------------------------|---------------------|
| Estland                | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia   | Trimetazidin                    | ZIDMETIN            | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Finland                | Actavis Group PTC ehf.<br>Reykjavikurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformin                       | Metformin Actavis   | 500 mg | Depottablet                            | Oral anvendelse     |
| Finland                | Actavis Group PTC ehf.<br>Reykjavikurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformin                       | Metformin Actavis   | 750 mg | Depottablet                            | Oral anvendelse     |
| Finland                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Fluconazol                      | Fluconazol Bluefish | 50 mg  | Kapsel, hård                           | Oral anvendelse     |
| Finland                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Fluconazol                      | Fluconazol Bluefish | 150 mg | Kapsel, hård                           | Oral anvendelse     |
| Finland                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden     | Fluconazol                      | Fluconazol Bluefish | 200 mg | Kapsel, hård                           | Oral anvendelse     |
| Finland                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                      | Eletriptan                      | Eletriptan Mylan    | 40 mg  | Filmoverttrukket<br>tablet             | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                        | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>   | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|--------------------------------------------------------------------------|-----------------------------------------|------------------|---------------|---------------------------|----------------------------|
| Finland                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Repaglinid                              | Repaglinid Mylan | 0,5 mg        | Tablet                    | Oral anvendelse            |
| Finland                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Repaglinid                              | Repaglinid Mylan | 1 mg          | Tablet                    | Oral anvendelse            |
| Finland                        | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Repaglinid                              | Repaglinid Mylan | 2 mg          | Tablet                    | Oral anvendelse            |
| Finland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan                               | VALSARTAN ORION  | 40 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |
| Finland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan                               | VALSARTAN ORION  | 80 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |
| Finland                        | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan                               | VALSARTAN ORION  | 160 mg        | Filmovertrukket<br>tablet | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                 | Internationalt<br>generisk navn | Særnavn                                         | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------|---------------------------------|-------------------------------------------------|--------|---------------------------|---------------------|
| Finland                | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland  | Valsartan                       | VALSARTAN ORION                                 | 320 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Finland                | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany          | Desloratadin                    | Desloratadine<br>Ratiopharm                     | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Finland                | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany          | Desloratadin                    | Desloratadine<br>Ratiopharm                     | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Frankrig               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France | Escitalopram                    | ESCITALOPRAM ABBOTT<br>5mg, comprimé pelliculé  | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France | Escitalopram                    | ESCITALOPRAM ABBOTT<br>10mg, comprimé pelliculé | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France | Escitalopram                    | ESCITALOPRAM ABBOTT<br>15mg, comprimé pelliculé | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                            | Internationalt<br>generisk navn | Særnavn                                            | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------|---------|---------------------------|---------------------|
| Frankrig               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France            | Escitalopram                    | ESCITALOPRAM ABBOTT<br>20mg, comprimé pelliculé    | 20 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | ACCORD HEALTHCARE<br>France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France | Ropinirol                       | Ropinirole Accord<br>0,25mg, comprimé<br>pelliculé | 0,25 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | ACCORD HEALTHCARE<br>France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France | Ropinirol                       | Ropinirole Accord 0,5mg,<br>comprimé pelliculé     | 0,5 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | ACCORD HEALTHCARE<br>France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France | Ropinirol                       | Ropinirole Accord 1mg,<br>comprimé pelliculé       | 1 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | ACCORD HEALTHCARE<br>France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France | Ropinirol                       | Ropinirole Accord 2mg,<br>comprimé pelliculé       | 2 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                    | Internationalt<br>generisk navn | Særnavn                                                    | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------|--------|---------------------------|---------------------|
| Frankrig               | ACCORD HEALTHCARE<br>France SAS<br>45 Rue de Fbg de Roubaix<br>59000 Lille<br>France         | Ropinirol                       | Ropinirole Accord 5mg,<br>comprimé pelliculé               | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | ESCITALOPRAM BROWN<br>5 mg, comprimé pelliculé<br>sécable  | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | ESCITALOPRAM BROWN<br>10 mg, comprimé<br>pelliculé sécable | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | ESCITALOPRAM BROWN<br>15 mg, comprimé<br>pelliculé sécable | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | ESCITALOPRAM BROWN<br>20 mg, comprimé<br>pelliculé sécable | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                     | Internationalt<br>generisk navn | Særnavn                                                    | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------|--------|---------------------------|---------------------|
| Frankrig               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom  | Ebastin                         | EBASTINE BROWN &<br>BURK 10 mg, comprimé<br>orodispersible | 10 mg  | Smeltetablet              | Oral anvendelse     |
| Frankrig               | Cristers<br>22, quai Galliéni<br>92150 Suresnes<br>France                                     | Desloratadin                    | DES LorATADINE<br>CRISTERS<br>5 mg<br>comprimé pelliculé   | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Cristers<br>22, quai Galliéni<br>92150 Suresnes<br>France                                     | Ibuprofen                       | IBUPROFENE CRISTERS<br>400 mg<br>comprimé pelliculé        | 400 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Laboratoires Biogaran<br>15, boulevard Charles de<br>Gaulle<br>92707 Colombes Cedex<br>France | Ebastin                         | EBASTINE BIOGARAN 10<br>mg comprimé pelliculé              | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Laboratoires Biogaran<br>15, boulevard Charles de<br>Gaulle<br>92707 Colombes Cedex<br>France | Ebastin                         | EBASTINE BIOGARAN 10<br>mg comprimé<br>orodispersible      | 10 mg  | Smeltetablet              | Oral anvendelse     |
| Frankrig               | Laboratoires GERDA<br>24 rue Erlanger<br>75016 PARIS<br>France                                | Desloratadin                    | DES LorATADINE ARROW<br>5 mg<br>comprimé pelliculé         | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                | Internationalt<br>generisk navn | Særnavn                                                                | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Frankrig               | Medipha Sante<br>Les Fjords - Immeuble Oslo<br>19 avenue de Norvège<br>91953 Courtaboeuf Cedex<br>France | Tramadol/paracetamol            | TRAMADOL<br>PARACETAMOL NIALEX<br>37,5 mg/325 mg<br>comprimé pelliculé | 37,5 mg/325<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Medipha Sante<br>Les Fjords - Immeuble Oslo<br>19 avenue de Norvège<br>91953 Courtaboeuf Cedex<br>France | Desloratadin                    | DES LorATADINE GNR<br>5 mg<br>comprimé pelliculé                       | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                   | Rizatriptan                     | RIZATRIPTAN MYLAN<br>5mg, orodispersible<br>tablet                     | 5 mg              | Smeltetablet              | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                   | Rizatriptan                     | RIZATRIPTAN MYLAN 10<br>mg, orodispersible tablet                      | 10 mg             | Smeltetablet              | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                   | Ebastin                         | EBASTINE MYLAN 10mg,<br>film-coated tablet                             | 10 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                   | Ebastin                         | EBASTINE MYLAN 10mg,<br>orodispersible tablet                          | 10 mg             | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                              | Internationalt<br>generisk navn | Særnavn                                                  | Styrke  | Lægemiddelform                         | Administrationsmåde |
|------------------------|------------------------------------------------------------------------|---------------------------------|----------------------------------------------------------|---------|----------------------------------------|---------------------|
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Trimetazidin                    | TRIMETAZIDINE MYLAN<br>35 mg Modified Release<br>Tablets | 35 mg   | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Candesartan                     | CANDESARTAN MYLAN 32<br>mg, comprimé secable             | 32 mg   | Tablet                                 | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Donepezil                       | DONEPEZIL MYLAN 5<br>mg, orodispersible tablet           | 5 mg    | Smeltetablet                           | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Donepezil                       | DONEPEZIL MYLAN 10<br>mg, orodispersible tablet          | 10 mg   | Smeltetablet                           | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Esomeprazol                     | ESOMEPRAZOLE MYLAN<br>PHARMA 20mg, DR<br>capsule         | 20 mg   | Enterokapsel, hård                     | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Esomeprazol                     | ESOMEPRAZOLE MYLAN<br>PHARMA 40mg, DR<br>capsule         | 40 mg   | Enterokapsel, hård                     | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France | Desmopressin                    | DESMOPRESSINE MYLAN<br>60 µg, orodispersible<br>tablet   | 0,06 mg | Smeltetablet                           | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                            | Internationalt<br>generisk navn | Særnavn                                                 | Styrke  | Lægemiddelform | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------------|---------|----------------|---------------------|
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France               | Desmopressin                    | DESMOPRESSINE MYLAN<br>120 µg, orodispersible<br>tablet | 0,12 mg | Smeltetablet   | Oral anvendelse     |
| Frankrig               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France               | Desmopressin                    | DESMOPRESSINE MYLAN<br>240 µg, orodispersible<br>tablet | 0,24 mg | Smeltetablet   | Oral anvendelse     |
| Frankrig               | Ranbaxy Pharmacie<br>Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Aciclovir                       | Aciclovir Ranbaxy 800<br>mg, comprimé                   | 800 mg  | Tablet         | Oral anvendelse     |
| Frankrig               | Ranbaxy Pharmacie<br>Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Aciclovir                       | Aciclovir Ranbaxy 200<br>mg, comprimé                   | 200 mg  | Tablet         | Oral anvendelse     |
| Frankrig               | Ranbaxy Pharmacie<br>Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Aciclovir                       | Aciclovir Almus 200 mg,<br>comprimé                     | 200 mg  | Tablet         | Oral anvendelse     |
| Frankrig               | Ranbaxy Pharmacie<br>Generiques<br>11-15 Quai Dion Bouton<br>92800 Puteaux<br>France | Alendroninsyre                  | Acide Alendronique<br>Ranbaxy 70 mg,<br>comprimé        | 70 mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                     | Internationalt<br>generisk navn | Særnavn                                                    | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------|--------|---------------------------|---------------------|
| Frankrig               | Sanofi Aventis France<br>1-13 bd Romain Rolland<br>75159 Paris Cedex 14<br>France                             | Ebastin                         | EBASTINE ZENTIVA 10<br>mg comprimé pelliculé               | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Sanofi Aventis France<br>1-13 bd Romain Rolland<br>75159 Paris Cedex 14<br>France                             | Ebastin                         | EBASTINE ZENTIVA 10<br>mg comprimé<br>orodispersible       | 10 mg  | Smeltetablet              | Oral anvendelse     |
| Frankrig               | Teva Sante<br>Cœur Défense - 100-110<br>Esplanade du Général de<br>Gaulle<br>92931 La Défense Cedex<br>France | Desloratadin                    | DES LorATADINE TEVA<br>SANTE<br>5 mg<br>comprimé pelliculé | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                                       | Ebastin                         | EBOUDA 10 mg<br>comprimé pelliculé                         | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                                       | Ebastin                         | EBARREN 10 mg<br>comprimé pelliculé                        | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                                       | Ebastin                         | EBONDE 10 mg<br>comprimé pelliculé                         | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                               | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                               | <b>Styrke</b>     | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------------------------------------------|-------------------|---------------------------|----------------------------|
| Frankrig                       | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                         | Ebastin                                 | EBONTAN 10 mg<br>comprimé orodispersible                                     | 10 mg             | Smeltetablet              | Oral anvendelse            |
| Frankrig                       | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                         | Ebastin                                 | EBACHOI 10 mg<br>comprimé orodispersible                                     | 10 mg             | Smeltetablet              | Oral anvendelse            |
| Frankrig                       | Venipharm SAS<br>4 Bureaux de la Colline<br>92213 Saint-Cloud<br>France                         | Ibuprofen                               | IBUPROFENE ZYDUS<br>FRANCE 200 mg<br>comprimé pelliculé                      | 200 mg            | Filmovertrukket<br>tablet | Oral anvendelse            |
| Frankrig                       | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Ibuprofen                               | IBUPROFENE ZYDUS<br>FRANCE 400 mg<br>comprimé pelliculé                      | 400 mg            | Filmovertrukket<br>tablet | Oral anvendelse            |
| Frankrig                       | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Tramadol/paracetamol                    | TRAMADOL<br>PARACETAMOL ZYDUS<br>FRANCE 37,5 mg/325<br>mg comprimé pelliculé | 37,5 mg/325<br>mg | Filmovertrukket<br>tablet | Oral anvendelse            |
| Frankrig                       | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Ibuprofen                               | IBUPROFENE ZF 400 mg<br>comprimé pelliculé                                   | 400 mg            | Filmovertrukket<br>tablet | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                       | Internationalt<br>generisk navn | Særnavn                                                    | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------|--------|---------------------------|---------------------|
| Frankrig               | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Desloratadin                    | DESLORATADINE ZYDUS<br>5 mg comprimé pelliculé             | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Escitalopram                    | ESCITALOPRAM ZYDUS 5<br>mg, comprimé pelliculé             | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Escitalopram                    | ESCITALOPRAM ZYDUS<br>10 mg, comprimé<br>pelliculé sécable | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Escitalopram                    | ESCITALOPRAM ZYDUS<br>15 mg, comprimé<br>pelliculé sécable | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Frankrig               | Zydus France<br>Zacles Hautes Patures<br>25 Rue des Peupliers<br>92752 Nanterre Cedex<br>France | Escitalopram                    | ESCITALOPRAM ZYDUS<br>20 mg, comprimé<br>pelliculé sécable | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                      | Styrke  | Lægemiddelform             | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------|---------|----------------------------|---------------------|
| Tyskland               | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | ALENDRONIC ACID<br>ACCORD 70MG               | 70 mg   | Tablet                     | Oral anvendelse     |
| Tyskland               | betapharm Arzneimittel<br>GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany                                       | Levetiracetam                   | Levetiracetam beta 250<br>mg, Filmdabletten  | 250 mg  | Filmoverttrukket<br>tablet | Oral anvendelse     |
| Tyskland               | betapharm Arzneimittel<br>GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany                                       | Levetiracetam                   | Levetiracetam beta 500<br>mg, Filmdabletten  | 500 mg  | Filmoverttrukket<br>tablet | Oral anvendelse     |
| Tyskland               | betapharm Arzneimittel<br>GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany                                       | Levetiracetam                   | Levetiracetam beta 750<br>mg, Filmdabletten  | 750 mg  | Filmoverttrukket<br>tablet | Oral anvendelse     |
| Tyskland               | betapharm Arzneimittel<br>GmbH<br>Kobelweg 95<br>D-86156 Augsburg<br>Germany                                       | Levetiracetam                   | Levetiracetam beta 1000<br>mg, Filmdabletten | 1000 mg | Filmoverttrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn   | Særnavn                                                               | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|-----------------------------------|-----------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                        | Irbesartan Tablets<br>75mg                                            | 75 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                        | Irbesartan Tablets<br>150mg                                           | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                        | Irbesartan Tablets<br>300 mg                                          | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan HCTZ Fair-<br>Med 150+12,5 mg<br>Filmdabletten             | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan HCTZ Fair-<br>Med 300+12,5 mg<br>Filmdabletten             | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan HCTZ Fair-<br>Med 300+25 mg<br>Filmdabletten               | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid  | Valsartan/HCTZ Fair-Med<br>Healthcare 160 mg/12.5<br>mg Filmdabletten | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn  | Særnavn                                                               | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/HCTZ Fair-Med<br>Healthcare 320 mg/12,5<br>mg Filmtabletten | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/HCTZ Fair-Med<br>Healthcare 320 mg/25<br>mg Filmtabletten   | 320 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaxin                       | Venlafaxin Fair-Med 37,5<br>mg Hartkapseln,<br>retardiert             | 37,5 mg           | Depotkapsel, hård         | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaxin                       | Venlafaxin Fair-Med 75<br>mg Hartkapseln,<br>retardiert               | 75 mg             | Depotkapsel, hård         | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaxin                       | Venlafaxin Fair-Med 150<br>mg Hartkapseln,<br>retardiert              | 150 mg            | Depotkapsel, hård         | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                    | Ciprofloxacin Fair-Med<br>Healthcare 500 mg<br>Filmtabletten          | 500 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                    | Ciprofloxacin Fair-Med<br>Healthcare 750 mg<br>Filmtabletten          | 750 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                       | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                               | <b>Styrke</b>     | <b>Lægemiddelform</b>      | <b>Administrationsmåde</b> |
|--------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------------------------------------------|-------------------|----------------------------|----------------------------|
| Tyskland                       | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany             | Ciprofloxacin                           | Ciprofloxacin Fair-Med<br>Healthcare 250 mg<br>Filmdabletten                 | 250 mg            | Filmovertrukket<br>tablett | Oral anvendelse            |
| Tyskland                       | Heumann Pharma GmbH &<br>Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan                              | Irbesartan Heumann 75<br>mg Filmdabletten                                    | 75 mg             | Filmovertrukket<br>tablett | Oral anvendelse            |
| Tyskland                       | Heumann Pharma GmbH &<br>Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan                              | Irbesartan Heumann 150<br>mg Filmdabletten                                   | 150 mg            | Filmovertrukket<br>tablett | Oral anvendelse            |
| Tyskland                       | Heumann Pharma GmbH &<br>Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan                              | Irbesartan Heumann 300<br>mg Filmdabletten                                   | 300 mg            | Filmovertrukket<br>tablett | Oral anvendelse            |
| Tyskland                       | Heumann Pharma GmbH &<br>Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan/hydrochlorot<br>hiazid       | Irbesartan/Hydrochlorothi<br>azid Heumann 150<br>mg/12.5 mg<br>Filmdabletten | 150 mg/12,5<br>mg | Filmovertrukket<br>tablett | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                  | Internationalt<br>generisk navn   | Særnavn                                                                      | Styrke            | Lægemiddelform              | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------|-------------------|-----------------------------|---------------------|
| Tyskland               | Heumann Pharma GmbH &<br>Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                    | Irbesartan/hydrochlorot<br>hiazid | Irbesartan/Hydrochlorothi<br>azid Heumann 300<br>mg/12.5 mg<br>Filmdabletten | 300 mg/12,5<br>mg | Filmoverttrukket<br>tablett | Oral anvendelse     |
| Tyskland               | Heumann Pharma GmbH &<br>Co. Generica KG<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                    | Irbesartan/hydrochlorot<br>hiazid | Irbesartan/Hydrochlorothi<br>azid Heumann 300<br>mg/25 mg Filmdabletten      | 300 mg/25<br>mg   | Filmoverttrukket<br>tablett | Oral anvendelse     |
| Tyskland               | Hormosan Pharma GmbH<br>Wilhelmshoeher Str. 106<br>D-60389 Frankfurt<br>06 Hessen<br>Germany               | Cefpodoximproxetil                | Cefpodoxim-<br>Hormosan<br>200mg<br>Filmdabletten                            | 200 mg            | Filmoverttrukket<br>tablett | Oral anvendelse     |
| Tyskland               | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16<br>0PF<br>United Kingdom | Trimetazidinhydrochlorid          | Lupamadazine 35 mg<br>Retardtabletten                                        | 35 mg             | Depottablett                | Oral anvendelse     |
| Tyskland               | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany                                     | Escitalopram                      | Escitalopram-Micro Labs<br>5 mg Filmdabletten                                | 5 mg              | Filmoverttrukket<br>tablett | Oral anvendelse     |
| Tyskland               | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany                                     | Escitalopram                      | Escitalopram-Micro Labs<br>10 mg Filmdabletten                               | 10 mg             | Filmoverttrukket<br>tablett | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                              | Internationalt<br>generisk navn | Særnavn                                          | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|------------------------------------------------------------------------|---------------------------------|--------------------------------------------------|--------|---------------------------|---------------------|
| Tyskland               | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany | Escitalopram                    | Escitalopram-Micro Labs<br>15 mg Filmtabletten   | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Micro Labs GmbH<br>Lyoner Str. 14<br>D-60528 Frankfurt/Main<br>Germany | Escitalopram                    | Escitalopram-Micro Labs<br>20 mg Filmtabletten   | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany      | Repaglinid                      | Repaglinid Mylan 0,5 mg<br>Tabletten             | 0,5 mg | Tablet                    | Oral anvendelse     |
| Tyskland               | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany      | Repaglinid                      | Repaglinid Mylan 1 mg<br>Tabletten               | 1 mg   | Tablet                    | Oral anvendelse     |
| Tyskland               | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany      | Repaglinid                      | Repaglinid Mylan 2 mg<br>Tabletten               | 2 mg   | Tablet                    | Oral anvendelse     |
| Tyskland               | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany      | Rizatriptan                     | Rizatriptan Mylan dura 5<br>mg Schmelztabletten  | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Tyskland               | Mylan dura GmbH<br>Wittichstrasse 6<br>64295 Darmstadt<br>Germany      | Rizatriptan                     | Rizatriptan Mylan dura 10<br>mg Schmelztabletten | 10 mg  | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                    | Internationalt<br>generisk navn | Særnavn                                    | Styrke | Lægemiddelform              | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------|--------|-----------------------------|---------------------|
| Tyskland               | Panacea Biotech Germany<br>GmbH<br>Landshuter Allee 8-10<br>D-80637 München<br>Germany                                                       | Tacrolimus                      | Tacpan 0.5 mg<br>Hartkapseln               | 0,5 mg | Kapsel, hård                | Oral anvendelse     |
| Tyskland               | Panacea Biotech Germany<br>GmbH<br>Landshuter Allee 8-10<br>D-80637 München<br>Germany                                                       | Tacrolimus                      | Tacpan 1 mg Hartkapseln                    | 1 mg   | Kapsel, hård                | Oral anvendelse     |
| Tyskland               | Panacea Biotech Germany<br>GmbH<br>Landshuter Allee 8-10<br>D-80637 München<br>Germany                                                       | Tacrolimus                      | Tacpan 5 mg Hartkapseln                    | 5 mg   | Kapsel, hård                | Oral anvendelse     |
| Tyskland               | Stadapharm GmbH<br>Stadastr. 2-18<br>D-61118 Bad Vilbel<br>Germany                                                                           | Entacapon                       | Entacapon STADA 200<br>mg Filmdabletten    | 200 mg | Filmoverttrukket<br>tablett | Oral anvendelse     |
| Tyskland               | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe<br>Commercial Centre,<br>Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | Irbesartan                      | Irbesartan Unichem 150<br>mg Filmdabletten | 150 mg | Filmoverttrukket<br>tablett | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                    | Internationalt<br>generisk navn   | Særnavn                                    | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------------------------------|-------------------|---------------------------|---------------------|
| Tyskland               | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe<br>Commercial Centre,<br>Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | Irbesartan                        | Irbesartan Unichem 300<br>mg Filmtabletten | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                          | Irbesartan/hydrochlorot<br>hiazid | Irbesartan +<br>Hidroclorotiazida Welding  | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                          | Irbesartan/hydrochlorot<br>hiazid | Irbesartan +<br>Hidroclorotiazida Welding  | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                          | Irbesartan/hydrochlorot<br>hiazid | Irbesartan +<br>Hidroclorotiazida Welding  | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                          | Irbesartan                        | Irbesartan Welding                         | 75 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Tyskland               | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                                                          | Irbesartan                        | Irbesartan Welding                         | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                          | Internationalt<br>generisk navn | Særnavn                                                            | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------------|--------|---------------------------|---------------------|
| Tyskland               | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                | Irbesartan                      | Irbesartan Welding                                                 | 300 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Grækenland             | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Escitalopramoxalat              | Savandra                                                           | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Grækenland             | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Escitalopramoxalat              | Savandra                                                           | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Grækenland             | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Escitalopramoxalat              | Savandra                                                           | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Grækenland             | Abbott Laboratories<br>Hellas ABEE<br>Agiou Dimitriou 63<br>Alimos 17456<br>Greece | Escitalopramoxalat              | Savandra                                                           | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Grækenland             | Genepharma S.A.<br>18 Km Marathon Avenue,<br>15351 Pallini<br>Greece               | Desloratadin                    | Desloratadine/Genepharma<br>5 mg δισκία<br>επικαλυμμένα με υμένιο, | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                        | Internationalt<br>generisk navn | Særnavn                                                                | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------|--------|---------------------------|---------------------|
| Grækenland             | Genepharma S.A.<br>18 Km Marathon Avenue,<br>15351 Pallini<br>Greece                             | Desloratadin                    | Desloratadine/Genepharma<br>m 2,5 mg δισκία<br>διασπειρόμενα στο στόμα | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Grækenland             | Genepharma S.A.<br>18 Km Marathon Avenue,<br>15351 Pallini<br>Greece                             | Desloratadin                    | Desloratadine/Genepharma<br>m 5 mg δισκία<br>διασπειρόμενα στο στόμα   | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Grækenland             | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece | Donepezilhydrochlorid           | DONEPEZIL/<br>GENERICS                                                 | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Grækenland             | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece | Donepezilhydrochlorid           | DONEPEZIL/<br>GENERICS                                                 | 10 mg  | Smeltetablet              | Oral anvendelse     |
| Grækenland             | Generics Pharma Hellas Ltd<br>577a Vouliagmenis Avenue<br>Argyroupoli<br>164-51 Athens<br>Greece | Esomeprazolmagnesium            | ESOMEPRAZOLE/<br>GENERICS                                              | 40 mg  | Depotkapsel               | Oral anvendelse     |
| Grækenland             | Sieger Pharma A.E.<br>Marathonos Avenue 106<br>Pikermi 19009<br>Greece                           | Desloratadin                    | Desloratadine/Sieger                                                   | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                            | Styrke | Lægemiddelform             | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------------|--------|----------------------------|---------------------|
| Grækenland             | Sieger Pharma A.E.<br>Marathonos Avenue 106<br>Pikermi 19009<br>Greece                      | Desloratadin                    | Desloratadine/Sieger                                               | 2,5 mg | Smeltetablet               | Oral anvendelse     |
| Grækenland             | Sieger Pharma A.E.<br>Marathonos Avenue 106<br>Pikermi 19009<br>Greece                      | Desloratadin                    | Desloratadine/Sieger                                               | 5 mg   | Smeltetablet               | Oral anvendelse     |
| Ungarn                 | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland             | Metforminhydrochlorid           | Gluforlyn XR 500 mg<br>retard tableta                              | 500 mg | Depottablet                | Oral anvendelse     |
| Ungarn                 | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Luxembourg               | Desloratadin                    | Alvotadin 5 mg<br>filmtabletta                                     | 5 mg   | Filmoverttrukket<br>tablet | Oral anvendelse     |
| Ungarn                 | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Luxembourg               | Desloratadin                    | Alvotadin 2.5 mg szájban<br>diszpergálódó tableta                  | 2,5 mg | Smeltetablet               | Oral anvendelse     |
| Ungarn                 | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Luxembourg               | Desloratadin                    | Alvotadin 5 mg szájban<br>diszpergálódó tableta                    | 5 mg   | Smeltetablet               | Oral anvendelse     |
| Ungarn                 | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomeprazol Mylan 20<br>mg gyomornedv-ellenálló<br>kemény kapszula | 20 mg  | Enterokapsel, hård         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                            | Styrke | Lægemiddelform             | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------------|--------|----------------------------|---------------------|
| Ungarn                 | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomeprazol Mylan 40<br>mg gyomornedv-ellenálló<br>kemény kapszula | 40 mg  | Enterokapsel, hård         | Oral anvendelse     |
| Ungarn                 | Glenmark Pharmaceuticals<br>s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic   | Trimetazidindihydrochlorid      | Apstar 35 mg retard<br>tabletta                                    | 35 mg  | Depottablet                | Oral anvendelse     |
| Ungarn                 | Goodwill Pharma Kft.<br>H-6724 Szeged<br>Cserzy Mihály u. 32.<br>Hungary                    | Desloratadin                    | Inaller 5 mg filmdtabletta                                         | 5 mg   | Filmoverttrukket<br>tablet | Oral anvendelse     |
| Ungarn                 | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                      | Trimetazidin                    | Trimetazidine Mylan 35<br>mg retard tablett                        | 35 mg  | Depottablet                | Oral anvendelse     |
| Ungarn                 | Sandoz Hungária Kft.<br>H-1114 Budapest<br>Bartók Béla út 43-47.<br>Hungary                 | Trimetazidindihydrochlorid      | Trimetazidine Sandoz 35<br>mg retard tablett                       | 35 mg  | Depottablet                | Oral anvendelse     |
| Ungarn                 | Teva Gyógyszergyár Zrt.<br>H-4042 Debrecen<br>Pallagi út 13.<br>Hungary                     | Desloratadin                    | Desloratadin Teva 2.5 mg<br>szájban diszpergálódó<br>tablett       | 2,5 mg | Smeltetablet               | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                                     | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------------|---------|---------------------------|---------------------|
| Ungarn                 | Teva Gyógyszergyár Zrt.<br>H-4042 Debrecen<br>Pallagi út 13.<br>Hungary                                            | Desloratadin                    | Desloratadin Teva 5 mg<br>szájban diszpergálódó<br>tabletta | 5 mg    | Smeltetablet              | Oral anvendelse     |
| Island                 | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                                                   | Desloratadin                    | Desloratadine ratiopharm                                    | 5 mg    | Smeltetablet              | Oral anvendelse     |
| Irland                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirolhydrochlorid           | Ropinirole 0.25 mg Film-<br>coated Tablets                  | 0,25 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirolhydrochlorid           | Ropinirole 0.5 mg Film-<br>coated Tablets                   | 0,5 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirolhydrochlorid           | Ropinirole 1 mg Film-<br>coated Tablets                     | 1 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn  | Særnavn                                                                              | Styrke            | Lægemiddelform            | Administrationsmåde |
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| Irland                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirolhydrochlorid            | Ropinirole 2 mg Film-<br>coated Tablets                                              | 2 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirolhydrochlorid            | Ropinirole 5 mg Film-<br>coated Tablets                                              | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                   | Alendronic Acid Once<br>Weekly 70 mg Tablets                                         | 70 mg             | Tablet                    | Oral anvendelse     |
| Irland                 | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                        | Valsartan/hydrochlorothi<br>azid | Valsartan/Hydrochlorothi<br>azide Fair-Med 160<br>mg/12.5 mg film-coated<br>tablets. | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                        | Valsartan/hydrochlorothi<br>azid | Valsartan/Hydrochlorothi<br>azide Fair-Med 320<br>mg/12.5 mg film-coated<br>tablets  | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn  | Særnavn                                                                           | Styrke          | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------------|-----------------|---------------------------|---------------------|
| Irland                 | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                                         | Valsartan/hydrochlorothi<br>azid | Valsartan/Hydrochlorothi<br>azide Fair-Med 320<br>mg/25 mg film-coated<br>tablets | 320 mg/25<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom             | Fexofenadinhydrochlorid          | Fexofenadine 120 mg<br>film-coated tablets                                        | 120 mg          | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom             | Fexofenadinhydrochlorid          | Fexofenadine 180 mg<br>film-coated tablets                                        | 180 mg          | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Donepezil                        | Aripil Orotab 5mg<br>Orodispersible Tablet                                        | 5 mg            | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn                                                        | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------------------|--------|----------------|---------------------|
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Donepezil                       | Aripil Orotab 10mg<br>Orodispersible Tablet                    | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Esomeprazol                     | Esomeprazole Mylan 20<br>mg Gastro-resistant<br>Capsules, hard | 20 mg  | Enterokapsel   | Oral anvendelse     |
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Esomeprazol                     | Esomeprazole Mylan 40<br>mg Gastro-resistant<br>Capsules, hard | 40 mg  | Enterokapsel   | Oral anvendelse     |
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Candesartan                     | Candesartan Mylan 4mg<br>Tablets                               | 4 mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn                                                 | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------------|--------|---------------------------|---------------------|
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Candesartan                     | Candesartan Mylan 8 mg<br>Tablets                       | 8 mg   | Tablet                    | Oral anvendelse     |
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Candesartan                     | Candesartan Mylan 16<br>mg Tablets                      | 16 mg  | Tablet                    | Oral anvendelse     |
| Irland                 | McDermott Laboratories Ltd<br>t/a Gerard Laboratories<br>35/36 Baldoyle Industrial<br>Estate<br>Grange Road<br>Dublin 13<br>Ireland | Candesartan                     | Candesartan Mylan 32<br>mg Tablets                      | 32 mg  | Tablet                    | Oral anvendelse     |
| Irland                 | Morningside Healthcare<br>Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom                                    | Phenoxymethylpenicillin         | Phenoxymethylpenicillin<br>250mg Film-coated<br>Tablets | 250 mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                     | Internationalt<br>generisk navn | Særnavn                                       | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------|--------|---------------------------|---------------------|
| Irland                 | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | Amlodipinbesilat                | Amlodipine Niche 5mg<br>tablets               | 5 mg   | Tablet                    | Oral anvendelse     |
| Irland                 | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | Amlodipinbesilat                | Amlodipine Niche 10mg<br>Tablets              | 10 mg  | Tablet                    | Oral anvendelse     |
| Irland                 | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | Irbesartan                      | Irbesartan Niche 150mg<br>film coated tablets | 150 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | Irbesartan                      | Irbesartan Niche 300mg<br>film coated tablets | 300 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Irland                 | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom     | Clopidogrelhydrochlorid         | Clopidogrel 75mg film-<br>coated tablets      | 75 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                       | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------|--------|---------------------------|---------------------|
| Italien                | Accord Healthcare Italia<br>S.r.l.<br>Largo Esterle, 4<br>20052 Monza<br>Italy                                     | Metoclopramid                   | METOCLOPRAMIDE<br>ACCORD      | 10 mg  | Tablet                    | Oral anvendelse     |
| Italien                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | ALENDRONATO AHCL              | 10 mg  | Tablet                    | Oral anvendelse     |
| Italien                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | ALENDRONATO AHCL              | 70 mg  | Tablet                    | Oral anvendelse     |
| Italien                | Doc Generici SRL<br>Via Turati, 40<br>20121 Milano<br>Italy                                                        | Desloratadin                    | DESLORATADINA DOC<br>GENERICI | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Italien                | Doc Generici SRL<br>Via Turati, 40<br>20121 Milano<br>Italy                                                        | Desloratadin                    | DESLORATADINA DOC<br>GENERICI | 2,5 mg | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                      | Internationalt<br>generisk navn | Særnavn                       | Styrke | Lægemiddelform            | Administrationsmåde |
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| Italien                | Doc Generici SRL<br>Via Turati, 40<br>20121 Milano<br>Italy                    | Desloratadin                    | DESLOTATADINA DOC<br>GENERICI | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Italien                | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy | Valsartan                       | VALSOTEN                      | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Italien                | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy | Valsartan                       | VALSOTEN                      | 80 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Italien                | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy | Valsartan                       | VALSOTEN                      | 160 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Italien                | Farmaceutici Caber S.P.A.<br>Viale Citta' D'Europa, 681<br>00144 Rome<br>Italy | Valsartan                       | VALSOTEN                      | 320 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Esomeprazolmagnesium            | ESOMEPRAZOLO MYLAN            | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy                  | Esomeprazolmagnesium            | ESOMEPRAZOLO MYLAN            | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                     | Internationalt<br>generisk navn | Særnavn                             | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|---------------------------------------------------------------|---------------------------------|-------------------------------------|--------|----------------|---------------------|
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Rizatriptanbenzoat              | RIAZATRIPTAN MYLAN<br>GENERICIS     | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Rizatriptanbenzoat              | RIAZATRIPTAN MYLAN<br>GENERICIS     | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Donepezilhydrochlorid           | DONEPEZIL MYLAN<br>GENERICIS ITALIA | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Donepezilhydrochlorid           | DONEPEZIL MYLAN<br>GENERICIS ITALIA | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Repaglinid                      | REPAGLINIDE MYLAN                   | 0,5 mg | Tablet         | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Repaglinid                      | REPAGLINIDE MYLAN                   | 1 mg   | Tablet         | Oral anvendelse     |
| Italien                | Mylan S.P.A.<br>Via Vittor Pisani, 20<br>20124 Milan<br>Italy | Repaglinid                      | REPAGLINIDE MYLAN                   | 2 mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                           | Internationalt<br>generisk navn | Særnavn                              | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------|--------|----------------------------------------|---------------------|
| Italien                | Pensa Pharma S.P.A.<br>Via Rossellini Ippolito, 12<br>20124 Milan<br>Italy                                          | Alendroninsyre                  | Alendronato Pensa<br>70 mg compresse | 70 mg  | Tablet                                 | Oral anvendelse     |
| Italien                | Ranbaxy Italia S.P.A.<br>Piazza Filippo Meda, 4, 3<br>20121 - Milano<br>Italy                                       | Alendroninsyre                  | ALENDRONATO RANBAXY<br>ITALIA        | 70 mg  | Tablet                                 | Oral anvendelse     |
| Letland                | Sandoz Pharmaceuticals d.d.<br>Verovskova 57<br>Ljubljana SI-1000<br>Slovenia                                       | Trimetazidindihydrochlorid      | Zidmetin                             | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Litauen                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom  | Alendroninsyre                  | Alendronic acid Accord               | 70 mg  | Tablet                                 | Oral anvendelse     |
| Litauen                | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol                       | Ropinirole Lambada                   | 0,5 mg | Filmovertrukket<br>tablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                           | Internationalt<br>generisk navn | Særnavn              | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|--------|---------------------------|---------------------|
| Litauen                | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol                       | Ropinirole Lambada   | 1 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol                       | Ropinirole Lambada   | 2 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Lambda Therapeutic Limited<br>Sage House<br>319 Pinner Road, North<br>Harrow<br>Middlesex HA1 4HF<br>United Kingdom | Ropinirol                       | Ropinirole Lambada   | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                                  | Irbesartan                      | Irbesartanas Torrent | 75 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                                  | Irbesartan                      | Irbesartanas Torrent | 150 mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                            | Internationalt<br>generisk navn   | Særnavn                                      | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------|-----------------------------------|----------------------------------------------|-------------------|---------------------------|---------------------|
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan                        | Irbesartanas Torrent                         | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan/hydrochlorot<br>hiazid | Irbesartanas/Hidrochlorot<br>iazidas Torrent | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan/hydrochlorot<br>hiazid | Irbesartanas/Hidrochlorot<br>iazidas Torrent | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Litauen                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany   | Irbesartan/hydrochlorot<br>hiazid | Irbesartanas/Hidrochlorot<br>iazidas Torrent | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Luxembourg             | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Repaglinid                        | Repaglinide Mylan<br>Pharma 0,5 mg tabletten | 0,5 mg            | Tablet                    | Oral anvendelse     |
| Luxembourg             | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Repaglinid                        | Repaglinide Mylan<br>Pharma 1 mg tabletten   | 1 mg              | Tablet                    | Oral anvendelse     |
| Luxembourg             | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium | Repaglinid                        | Repaglinide Mylan<br>Pharma 2 mg tabletten   | 2 mg              | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn  | Særnavn                                                      | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|----------------------------------|--------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Luxembourg             | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium        | Esomeprazol                      | Esomeprazole Mylan                                           | 20 mg             | Enterokapsel, hård        | Oral anvendelse     |
| Luxembourg             | Mylan bvba/sprl<br>Terhulpsesteenweg 6A<br>1560 Hoeilaart<br>Belgium        | Esomeprazol                      | Esomeprazole Mylan                                           | 40 mg             | Enterokapsel, hård        | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/hydrochlorthiaz<br>id "Fair-Med" Coated<br>tablets | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/hydrochlorthiaz<br>id "Fair-Med" Coated<br>tablets | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/hydrochlorthiaz<br>id "Fair-Med" Coated<br>tablets | 320 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                    | Ciprofloxacin Fair-Med<br>Coated Tablets                     | 250 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                    | Ciprofloxacin Fair-Med<br>Coated Tablets                     | 500 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn   | Særnavn                                                                            | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                        | Irbesartan Fairmed 75mg<br>Film-coated Tablets                                     | 75 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                        | Irbesartan Fairmed<br>150mg Film-coated<br>Tablets                                 | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                        | Irbesartan Fairmed<br>300mg Film-coated<br>Tablets                                 | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan/Hydrochlorothi<br>azide Fairmed<br>150mg/12.5mg film-<br>coated tablets | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan/Hydrochlorothi<br>azide Fairmed<br>300mg/12.5mg film-<br>coated tablets | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan/Hydrochlorothi<br>azide Fairmed<br>300mg/25mg film-coated<br>tablets    | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaxin                        | Venlafaxine Fair-Med                                                               | 37,5 mg           | Depotkapsel, hård         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                 | Internationalt<br>generisk navn | Særnavn                                  | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------|--------|---------------------------|---------------------|
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                               | Venlafaxin                      | Venlafaxine Fair-Med                     | 75 mg  | Depotkapsel, hård         | Oral anvendelse     |
| Malta                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                               | Venlafaxin                      | Venlafaxine Fair-Med                     | 150 mg | Depotkapsel, hård         | Oral anvendelse     |
| Malta                  | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Clopidogrel                     | Clopidogrel 75mg Film-<br>coated Tablets | 75 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Malta                  | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Clopidogrel                     | Clopidogrel 75mg Coated<br>Tablets       | 75 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Norge                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                               | Fluconazol                      | Fluconazol Bluefish                      | 50 mg  | Kapsel, hård              | Oral anvendelse     |
| Norge                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                               | Fluconazol                      | Fluconazol Bluefish                      | 150 mg | Kapsel, hård              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn | Særnavn             | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|---------------------------------|---------------------|--------|---------------------------|---------------------|
| Norge                  | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden | Fluconazol                      | Fluconazol Bluefish | 200 mg | Kapsel, hård              | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Esomeprazol                     | Esomeprazol Mylan   | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Esomeprazol                     | Esomeprazol Mylan   | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Eletriptan                      | Eletriptan Mylan    | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Eletriptan                      | Eletriptan Mylan    | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Candesartancilexetil            | Kandrozid           | 4 mg   | tablet                    | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                  | Candesartancilexetil            | Kandrozid           | 8 mg   | tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                        | Internationalt<br>generisk navn | Særnavn                                           | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|------------------------------------------------------------------|---------------------------------|---------------------------------------------------|--------|----------------|---------------------|
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Candesartancilexetil            | Kandrozid                                         | 16 mg  | tablet         | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Candesartancilexetil            | Kandrozid                                         | 32 mg  | tablet         | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Candesartancilexetil            | Mylcande                                          | 8 mg   | tablet         | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Candesartancilexetil            | Mylcande                                          | 16 mg  | tablet         | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Candesartancilexetil            | Mylcande                                          | 32 mg  | tablet         | Oral anvendelse     |
| Norge                  | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden       | Rizatriptan                     | RIZATRIPTAN MYLAN 10<br>mg, orodispersible tablet | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Norge                  | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany | Desloratadin                    | Desloratadin Ratiopharm                           | 2,5 mg | Smeltetablet   | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                        | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>          | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------|---------------|---------------------------|----------------------------|
| Norge                          | ratiopharm GmbH<br>Graf-Arco-Strasse 3<br>D-89079 Ulm<br>Germany                         | Desloratadin                            | Desloratadin Ratiopharm | 5 mg          | Smeltetablet              | Oral anvendelse            |
| Polen                          | Abbott Laboratories Poland<br>Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Escitalopram                            | Savandra                | 5 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |
| Polen                          | Abbott Laboratories Poland<br>Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Escitalopram                            | Savandra                | 10 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |
| Polen                          | Abbott Laboratories Poland<br>Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Escitalopram                            | Savandra                | 15 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |
| Polen                          | Abbott Laboratories Poland<br>Sp. z o.o.<br>ul. Postępu 21B<br>02-676 Warszawa<br>Poland | Escitalopram                            | Savandra                | 20 mg         | Filmovertrukket<br>tablet | Oral anvendelse            |
| Polen                          | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland          | Metformin                               | Metformin SR Actavis    | 500 mg        | Filmovertrukket<br>tablet | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                       | Internationalt<br>generisk navn | Særnavn              | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------|---------------------------------|----------------------|--------|---------------------------|---------------------|
| Polen                  | Actavis Group PTC ehf.<br>Reykjavíkurvegi 76-78<br>220 Hafnarfjörður<br>Iceland | Metformin                       | Metformin SR Actavis | 750 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k.<br>Warszawy<br>Poland     | Desloratadin                    | Desada               | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Polen                  | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k.<br>Warszawy<br>Poland     | Desloratadin                    | Hitaxa Fast          | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Polen                  | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k.<br>Warszawy<br>Poland     | Desloratadin                    | Hitaxa               | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Polen                  | Adamed Sp. z o.o.<br>Pieńków 149<br>05-152 Czosnów k.<br>Warszawy<br>Poland     | Desloratadin                    | Hitaxa               | 5 mg   | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                       | Internationalt<br>generisk navn  | Særnavn                | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------|----------------------------------|------------------------|-------------------|---------------------------|---------------------|
| Polen                  | Aflofarm Farmacja Polska<br>Sp. z o.o.<br>ul. Partyzancka 133/151<br>95-200 Pabianice<br>Poland | Desloratadin                     | Teslor                 | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Aflofarm Farmacja Polska<br>Sp. z o.o.<br>ul. Partyzancka 133/151<br>95-200 Pabianice<br>Poland | Desloratadin                     | Teslor fast            | 5 mg              | Smeltetablet              | Oral anvendelse     |
| Polen                  | Aflofarm Farmacja Polska<br>Sp. z o.o.<br>ul. Partyzancka 133/151<br>95-200 Pabianice<br>Poland | Desloratadin                     | Teslor fast junior     | 2,5 mg            | Smeltetablet              | Oral anvendelse     |
| Polen                  | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                          | Trimetazidin                     | ApoTrimet PR           | 35 mg             | Depottablet               | Oral anvendelse     |
| Polen                  | Bio-Profil Polska Sp. z o.o.<br>Trakt Lubelski 135<br>04-790 Warszawa<br>Poland                 | Desloratadin                     | Desloratadine Peseri   | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                     | Valsartan/hydrochlorothi<br>azid | Valsartan HCT Fair-Med | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn   | Særnavn                 | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|-----------------------------------|-------------------------|-------------------|---------------------------|---------------------|
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid  | Valsartan HCT Fair-Med  | 320 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                     | Ciprofloxacin Fair-Med  | 250 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                     | Ciprofloxacin Fair-Med  | 500 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                        | Irbesartan Fair-Med     | 75 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                        | Irbesartan Fair-Med     | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan                        | Irbesartan Fair-Med     | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan HCT Fair-Med | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn   | Særnavn                 | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|-----------------------------------|-------------------------|-------------------|---------------------------|---------------------|
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Irbesartan/hydrochlorot<br>hiazid | Irbesartan HCT Fair-Med | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Irbesartan/hydrochlorot<br>hiazid | Irbesartan HCT Fair-Med | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Valsartan/hydrochlorothi<br>azid  | Valsartan HCT Fair-Med  | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Venlafaxin                        | VENLAFAXINE FAIR-MED    | 37,5 mg           | Depotkapsel, hård         | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Venlafaxin                        | VENLAFAXINE FAIR-MED    | 75 mg             | Depotkapsel, hård         | Oral anvendelse     |
| Polen                  | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                 | Venlafaxin                        | VENLAFAXINE FAIR-MED    | 150 mg            | Depotkapsel, hård         | Oral anvendelse     |
| Polen                  | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Candesartancilexetil              | Kangen                  | 8 mg              | Tablet                    | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                           | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>         | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|---------------------------------------------------------------------------------------------|-----------------------------------------|------------------------|---------------|---------------------------|----------------------------|
| Polen                          | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Candesartancilexetil                    | Kangen                 | 16 mg         | Tablet                    | Oral anvendelse            |
| Polen                          | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                  | Desloratadin                            | Desloratadine Labormed | 2,5 mg        | Smeltetablet              | Oral anvendelse            |
| Polen                          | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                  | Desloratadin                            | Desloratadine Labormed | 5 mg          | Smeltetablet              | Oral anvendelse            |
| Polen                          | Medicplast Polska Sp. z o.o<br>ul. Wólczyńska 232<br>01-919 Warszawa<br>Poland              | Desloratadin                            | Desalergo              | 5 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |
| Polen                          | Medicplast Polska Sp. z o.o<br>ul. Wólczyńska 232<br>01-919 Warszawa<br>Poland              | Desloratadin                            | Desalergo              | 2,5 mg        | Smeltetablet              | Oral anvendelse            |
| Polen                          | Medicplast Polska Sp. z o.o<br>ul. Wólczyńska 232<br>01-919 Warszawa<br>Poland              | Desloratadin                            | Desalergo              | 5 mg          | Smeltetablet              | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                   | Internationalt<br>generisk navn | Særnavn              | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|--------|---------------------------|---------------------|
| Polen                  | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                    | Valsartan                       | Valsartan Orion      | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                    | Valsartan                       | Valsartan Orion      | 80 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                    | Valsartan                       | Valsartan Orion      | 160 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                    | Valsartan                       | Valsartan Orion      | 320 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus | Desloratadin                    | Desloratadine Peseri | 2,5 mg | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                   | Internationalt<br>generisk navn | Særnavn              | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|--------|---------------------------|---------------------|
| Polen                  | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus | Desloratadin                    | Desloratadine Peseri | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Polen                  | Ranbaxy (Poland) Sp. z o.o.<br>Kubickiego 11<br>02-954 Warszawa<br>Poland                                   | Alendroninsyre                  | Alendran 70          | 70 mg  | Tablet                    | Oral anvendelse     |
| Polen                  | Sandoz GmbH<br>Biochemiestrasse 10<br>A-6250 Kundl<br>Austria                                               | Trimetazidin                    | Dimesar              | 35 mg  | Depottablet               | Oral anvendelse     |
| Polen                  | S-Lab Sp. z o.o.<br>ul. Kiełczowska 2<br>55-095 Mirków<br>Poland                                            | Desloratadin                    | Suprodeslon          | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | S-Lab Sp. z o.o.<br>ul. Kiełczowska 2<br>55-095 Mirków<br>Poland                                            | Desloratadin                    | Suprodeslon          | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Polen                  | S-Lab Sp. z o.o.<br>ul. Kiełczowska 2<br>55-095 Mirków<br>Poland                                            | Desloratadin                    | Suprodeslon          | 5 mg   | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                 | Internationalt<br>generisk navn | Særnavn               | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------|--------|---------------------------|---------------------|
| Polen                  | SymPhar Sp. z o.o.<br>ul. Włoska 1<br>00-777 Warszawa<br>Poland                                           | Desloratadin                    | Symdes                | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | Tactica Pharmaceuticals sp.<br>z o.o.<br>ul. Bankowa 4<br>44-100 Gliwice<br>Poland                        | Desloratadin                    | Goldesin              | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | US Pharmacia Sp. z o.o.<br>ul. Ziębicka 40<br>50-507 Wrocław<br>Poland                                    | Desloratadin                    | Aleric Deslo          | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Polen                  | US Pharmacia Sp. z o.o.<br>ul. Ziębicka 40<br>50-507 Wrocław<br>Poland                                    | Desloratadin                    | Aleric Deslo          | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Polen                  | US Pharmacia Sp. z o.o.<br>ul. Ziębicka 40<br>50-507 Wrocław<br>Poland                                    | Desloratadin                    | Aleric Deslo Active   | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Polen                  | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Clopidogrel                     | Clopidogrel Wockhardt | 75 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                         | Styrke            | Lægemiddelform                         | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------|-------------------|----------------------------------------|---------------------|
| Portugal               | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | Ácido alendrónico Accord        | 70 mg             | tablet                                 | Oral anvendelse     |
| Portugal               | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                                        | Cefpodoxim                      | Cefpodoxima Alkaloid            | 200 mg            | Tablet                                 | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                       | Tramadol/paracetamol            | Tramadol + Paracetamol<br>Brown | 37,5 mg/325<br>mg | Filmovertrukket<br>tablet              | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                       | Trimetazidin                    | Trimetazidina Brown             | 35 mg             | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                       | Escitalopram                    | Escitalopram Brown              | 10 mg             | Filmovertrukket<br>tablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                    | Internationalt<br>generisk navn | Særnavn            | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------|---------------------------------|--------------------|--------|---------------------------|---------------------|
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | Escitalopram Brown | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | Escitalopram Brown | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopram                    | Escitalopram Brown | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Ebastin                         | Ebastina Brown     | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Ebastin                         | Ebastina Brown     | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                                                                     | Internationalt<br>generisk navn | Særnavn             | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------|--------|---------------------------|---------------------|
| Portugal               | Daquimed - Comércio de<br>Produtos Farmacêuticos,<br>S.A.<br>Av. Associação Comercial e<br>Industrial de Gondomar, 330<br>- Zona Industrial da<br>Portelinha<br>4510-688 Fânzeres<br>Portugal | Quetiapin                       | Quetiapina Daquimed | 25 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Daquimed - Comércio de<br>Produtos Farmacêuticos,<br>S.A.<br>Av. Associação Comercial e<br>Industrial de Gondomar, 330<br>- Zona Industrial da<br>Portelinha<br>4510-688 Fânzeres<br>Portugal | Quetiapin                       | Quetiapina Daquimed | 100 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Daquimed - Comércio de<br>Produtos Farmacêuticos,<br>S.A.<br>Av. Associação Comercial e<br>Industrial de Gondomar, 330<br>- Zona Industrial da<br>Portelinha<br>4510-688 Fânzeres<br>Portugal | Quetiapin                       | Quetiapina Daquimed | 150 mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                                                                     | Internationalt<br>generisk navn  | Særnavn                                      | Styrke                   | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------------------|--------------------------|---------------------------|---------------------|
| Portugal               | Daquimed - Comércio de<br>Produtos Farmacêuticos,<br>S.A.<br>Av. Associação Comercial e<br>Industrial de Gondomar, 330<br>- Zona Industrial da<br>Portelinha<br>4510-688 Fânzeres<br>Portugal | Quetiapin                        | Quetiapina Daquimed                          | 200 mg                   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Daquimed - Comércio de<br>Produtos Farmacêuticos,<br>S.A.<br>Av. Associação Comercial e<br>Industrial de Gondomar, 330<br>- Zona Industrial da<br>Portelinha<br>4510-688 Fânzeres<br>Portugal | Quetiapin                        | Quetiapina Daquimed                          | 300 mg                   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                                                           | Levodopa/carbidopa/ent<br>acapon | Levodopa + Carbidopa +<br>Entacapona Generis | 50 mg/12,5<br>mg/200 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal                                                                                                           | Levodopa/carbidopa/ent<br>acapon | Levodopa + Carbidopa +<br>Entacapona Generis | 75 mg/18,75<br>mg/200 mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                           | Internationalt<br>generisk navn | Særnavn                                  | Styrke                  | Lægemiddelform         | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------|---------------------------------|------------------------------------------|-------------------------|------------------------|---------------------|
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/carbidopa/entacapon    | Levodopa + Carbidopa + Entacapon Generis | 100 mg/25 mg/200 mg     | Filmovertrukket tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/carbidopa/entacapon    | Levodopa + Carbidopa + Entacapon Generis | 125 mg/31,250 mg/200 mg | Filmovertrukket tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/carbidopa/entacapon    | Levodopa + Carbidopa + Entacapon Generis | 150 mg/37,5 mg/200 mg   | Filmovertrukket tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/carbidopa/entacapon    | Levodopa + Carbidopa + Entacapon Generis | 175 mg/43,75 mg/200 mg  | Filmovertrukket tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Levodopa/carbidopa/entacapon    | Levodopa + Carbidopa + Entacapon Generis | 200 mg/50 mg/200 mg     | Filmovertrukket tablet | Oral anvendelse     |
| Portugal               | Generis Farmacêutica, S. A.<br>Rua João de Deus, 19<br>2700-487 Amadora<br>Portugal | Entacapon                       | Entacapon Generis                        | 200 mg                  | Filmovertrukket tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                                             | Internationalt<br>generisk navn | Særnavn                       | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------|--------|----------------|---------------------|
| Portugal               | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n°<br>1370<br>3465-051 Campo de<br>Besteiros<br>Portugal                                                           | Desloratadin                    | Desloratadina Labesfal<br>OD  | 2,5 mg | Smeltetablet   | Oral anvendelse     |
| Portugal               | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n°<br>1370<br>3465-051 Campo de<br>Besteiros<br>Portugal                                                           | Desloratadin                    | Desloratadina Labesfal<br>OD  | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Portugal               | Labesfal, Genéricos, S.A.<br>Av. Dr. Afonso Costa, n°<br>1370<br>3465-051 Campo de<br>Besteiros<br>Portugal                                                           | Alendroninsyre                  | Ácido alendrónico<br>Labesfal | 70 mg  | tablet         | Oral anvendelse     |
| Portugal               | Laboratórios Anova -<br>Produtos Farmacêuticos,<br>Lda.<br>Rua Doutor António Loureiro<br>Borges<br>Edifício Arquiparque 1, R/C<br>Esq°<br>1499-016 Algés<br>Portugal | Donepezil                       | Donepezilo Anova              | 5 mg   | Smeltetablet   | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                                             | Internationalt<br>generisk navn | Særnavn           | Styrke | Lægemiddelform     | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------|--------|--------------------|---------------------|
| Portugal               | Laboratórios Anova -<br>Produtos Farmacêuticos,<br>Lda.<br>Rua Doutor António Loureiro<br>Borges<br>Edifício Arquiparque 1, R/C<br>Esqº<br>1499-016 Algés<br>Portugal | Donepezil                       | Donepezilo Anova  | 10 mg  | Smeltetablet       | Oral anvendelse     |
| Portugal               | Laboratórios Anova -<br>Produtos Farmacêuticos,<br>Lda.<br>Rua Doutor António Loureiro<br>Borges<br>Edifício Arquiparque 1, R/C<br>Esqº<br>1499-016 Algés<br>Portugal | Esomeprazol                     | Esomeprazol Anova | 20 mg  | Enterokapsel, hård | Oral anvendelse     |
| Portugal               | Laboratórios Anova -<br>Produtos Farmacêuticos,<br>Lda.<br>Rua Doutor António Loureiro<br>Borges<br>Edifício Arquiparque 1, R/C<br>Esqº<br>1499-016 Algés<br>Portugal | Esomeprazol                     | Esomeprazol Anova | 40 mg  | Enterokapsel, hård | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                            | Internationalt<br>generisk navn | Særnavn              | Styrke  | Lægemiddelform    | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|---------|-------------------|---------------------|
| Portugal               | Laboratórios Azevedos -<br>Indústria Farmacêutica, S.A.<br>Edifícios Azevedos - Estrada<br>Nacional 117-2, Alfragide<br>2614-504 Amadora<br>Portugal | Venlafaxin                      | Venlafaxina Azevedos | 37,5 mg | Depotkapsel, hård | Oral anvendelse     |
| Portugal               | Laboratórios Azevedos -<br>Indústria Farmacêutica, S.A.<br>Edifícios Azevedos - Estrada<br>Nacional 117-2, Alfragide<br>2614-504 Amadora<br>Portugal | Venlafaxin                      | Venlafaxina Azevedos | 75 mg   | Depotkapsel, hård | Oral anvendelse     |
| Portugal               | Laboratórios Azevedos -<br>Indústria Farmacêutica, S.A.<br>Edifícios Azevedos - Estrada<br>Nacional 117-2, Alfragide<br>2614-504 Amadora<br>Portugal | Venlafaxin                      | Venlafaxina Azevedos | 150 mg  | Depotkapsel, hård | Oral anvendelse     |
| Portugal               | Laboratórios Basi - Indústria<br>Farmacêutica, S.A<br>Parque Industrial Manuel<br>Lourenço Ferreira, Lote 15<br>3450-232 Mortágua<br>Portugal        | Fluconazol                      | Fluconazol Basi      | 50 mg   | Kapsel            | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                     | Internationalt<br>generisk navn | Særnavn                | Styrke | Lægemiddelform             | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------|--------|----------------------------|---------------------|
| Portugal               | Laboratórios Basi - Indústria<br>Farmacêutica, S.A<br>Parque Industrial Manuel<br>Lourenço Ferreira, Lote 15<br>3450-232 Mortágua<br>Portugal | Fluconazol                      | Fluconazol Basi        | 150 mg | Kapsel                     | Oral anvendelse     |
| Portugal               | Laboratórios Basi - Indústria<br>Farmacêutica, S.A<br>Parque Industrial Manuel<br>Lourenço Ferreira, Lote 15<br>3450-232 Mortágua<br>Portugal | Fluconazol                      | Fluconazol Basi        | 200 mg | Kapsel                     | Oral anvendelse     |
| Portugal               | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                                                                    | Desloratadin                    | Desloratadina Labormed | 5 mg   | Smeltetablet               | Oral anvendelse     |
| Portugal               | Labormed-Pharma, SA<br>Theodor Pallady, 44B<br>032266 Bucharest<br>Romania                                                                    | Desloratadin                    | Desloratadina Labormed | 2,5 mg | Smeltetablet               | Oral anvendelse     |
| Portugal               | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16<br>0PF<br>United Kingdom                                    | Cefpodoxim                      | Cefpodoxima Lupin      | 200 mg | Filmoverttrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn             | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------|--------|---------------------------|---------------------|
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Esomeprazol                     | Esomeprazol Mylan   | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Esomeprazol                     | Esomeprazol Mylan   | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatin                    | Atorvastatina Anova | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatin                    | Atorvastatina Anova | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn             | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------|--------|---------------------------|---------------------|
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatin                    | Atorvastatina Anova | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Atorvastatin                    | Atorvastatina Anova | 80 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Donepezil                       | Donepezilo Mylan    | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Donepezil                       | Donepezilo Mylan    | 10 mg  | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn             | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------|--------|----------------------------------------|---------------------|
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Trimetazidin                    | Trimetazidina Mylan | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Candesartan                     | Candesartan Mylan   | 4 mg   | Tablet                                 | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Candesartan                     | Candesartan Mylan   | 8 mg   | Tablet                                 | Oral anvendelse     |
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Candesartan                     | Candesartan Mylan   | 16 mg  | Tablet                                 | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn              | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------|--------|---------------------------|---------------------|
| Portugal               | Mylan, Lda.<br>Parque Expo, Edifício<br>Atlantis, Avenida D. João II,<br>Lote 1.06.2.2 C - 7.3 e 7.4<br>1990-095 Lisboa<br>Portugal | Candesartan                     | Candesartan Mylan    | 32 mg  | Tablet                    | Oral anvendelse     |
| Portugal               | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus                         | Desloratadin                    | Desloratadina Peseri | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Portugal               | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus                         | Desloratadin                    | Desloratadina Peseri | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Portugal               | Peseri Trading Limited<br>20 Queen Frederica Street<br>El-Greco House, office 301<br>1066 Nicosia<br>Cyprus                         | Desloratadin                    | Desloratadina Peseri | 2,5 mg | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                                                                           | Internationalt<br>generisk navn | Særnavn                     | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------------|--------|----------------------------------------|---------------------|
| Portugal               | Pharmakern Portugal -<br>Produtos Farmacêuticos,<br>Sociedade Unipessoal, Lda.<br>Edifício Atlas II, Av. José<br>Gomes Ferreira, N.º 11 - 3º,<br>Sala 31 - Miraflares<br>1495-139 Algés<br>Portugal | Trimetazidin                    | Trimetazidina<br>Pharmakern | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Portugal               | Ratiopharm - Comércio e<br>Indústria de Produtos<br>Farmacêuticos, Lda.<br>Lagoas Park, Edifício 5 A,<br>Piso 2<br>2740-245 Porto Salvo<br>Portugal                                                 | Desloratadin                    | Desloratadina<br>Ratiopharm | 2,5 mg | Smeltetablet                           | Oral anvendelse     |
| Portugal               | Ratiopharm - Comércio e<br>Indústria de Produtos<br>Farmacêuticos, Lda.<br>Lagoas Park, Edifício 5 A,<br>Piso 2<br>2740-245 Porto Salvo<br>Portugal                                                 | Desloratadin                    | Desloratadina<br>Ratiopharm | 5 mg   | Smeltetablet                           | Oral anvendelse     |
| Portugal               | Sandoz Farmaceutica Lda.<br>Avenida Professor Doutor<br>Cavaco Silva, n. 10E<br>Taguspark<br>2740-255 Porto Salvo<br>Portugal                                                                       | Trimetazidin                    | Trimetazidina Itraxel       | 35 mg  | Depottablet                            | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                           | Internationalt<br>generisk navn | Særnavn                              | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------|--------|---------------------------|---------------------|
| Portugal               | Teva Pharma - Produtos<br>Farmacêuticos,Lda.<br>Edifício Tejo, Rua Quinta do<br>Pinheiro, 16 - 6º<br>2790-143 Carnaxide<br>Portugal | Desloratadin                    | Desloratadina Teva                   | 2,5 mg | Smeltetablet              | Oral anvendelse     |
| Portugal               | Teva Pharma - Produtos<br>Farmacêuticos,Lda.<br>Edifício Tejo, Rua Quinta do<br>Pinheiro, 16 - 6º<br>2790-143 Carnaxide<br>Portugal | Desloratadin                    | Desloratadina Teva                   | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Rumænien               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                           | Escitalopram                    | SAVANDRA 5 mg<br>comprimate filmate  | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                           | Escitalopram                    | SAVANDRA 10 mg<br>comprimate filmate | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                           | Escitalopram                    | SAVANDRA 15 mg<br>comprimate filmate | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Abbott Products SAS<br>42 rue Rouget de Lisle<br>92150 Suresnes<br>France                                                           | Escitalopram                    | SAVANDRA 20 mg<br>comprimate filmate | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                    | Internationalt<br>generisk navn | Særnavn                                                      | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------|---------|---------------------------|---------------------|
| Rumænien               | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                                                  | Cefpodoxim                      | Forexo 200 mg<br>comprimate filmate                          | 200 mg  | Tablet                    | Oral anvendelse     |
| Rumænien               | Alvogen IPCo S.ar.l.<br>Rue Heienhaff 5<br>L-1736 Senningerberg<br>Luxembourg                                                | Desloratadin                    | Desloratadina Alvogen 5<br>mg comprimate filmate             | 5 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Levetiracetam                   | Levetiracetam Dr.<br>Reddy's, 250 mg,<br>comprimate filmate  | 250 mg  | Tablet                    | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Levetiracetam                   | Levetiracetam Dr.<br>Reddy's, 500mg,<br>comprimate filmate   | 500 mg  | Tablet                    | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Levetiracetam                   | Levetiracetam Dr.<br>Reddy's, 750 mg,<br>comprimate filmate  | 750 mg  | Tablet                    | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Levetiracetam                   | Levetiracetam Dr.<br>Reddy's, 1000 mg,<br>comprimate filmate | 1000 mg | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                    | Internationalt<br>generisk navn    | Særnavn                                                    | Styrke           | Lægemiddelform | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------------------------------|------------------|----------------|---------------------|
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Telmisartan                        | Telmisartan Dr. Reddy's<br>40 mg comprimate                | 40 mg            | Tablet         | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Telmisartan                        | Telmisartan Dr. Reddy's<br>80 mg comprimate                | 80 mg            | Tablet         | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Telmisartan/hydrochloro<br>thiazid | Telmisartan HCT Dr.<br>Reddy's 40 mg/12,5 mg<br>comprimate | 40 mg/12,5<br>mg | Tablet         | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Telmisartan/hydrochloro<br>thiazid | Telmisartan HCT Dr.<br>Reddy's 80 mg/12,5 mg<br>comprimate | 80 mg/12,5<br>mg | Tablet         | Oral anvendelse     |
| Rumænien               | Dr. Reddy's Laboratories<br>Romania SRL<br>71st-73rd Nicolae Caramfil,<br>Floor 5, Space 10, Sector 1,<br>Bucuresti, Romania | Telmisartan/hydrochloro<br>thiazid | Telmisartan HCT Dr.<br>Reddy's 80 mg/25 mg<br>comprimate   | 80 mg/25<br>mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                | Styrke | Lægemiddelform     | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------|--------|--------------------|---------------------|
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomeprazol Mylan 20<br>mg capsule<br>gastrorezistente | 20 mg  | Enterokapsel, hård | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomeprazol Mylan 40<br>mg capsule<br>gastrorezistente | 40 mg  | Enterokapsel, hård | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezilhydrochlorid           | Donepezil Mylan 5 mg<br>comprimate<br>orodispersabile  | 5 mg   | Smeltetablet       | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezilhydrochlorid           | Donepezil Mylan 10 mg<br>comprimate<br>orodispersabile | 10 mg  | Smeltetablet       | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Repaglinid                      | Repaglinida Generics 0.5<br>mg comprimate              | 0,5 mg | Tablet             | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Repaglinid                      | Repaglinida Generics 1<br>mg comprimate                | 1 mg   | Tablet             | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Repaglinid                      | Repaglinida Generics 2<br>mg comprimate                | 2 mg   | Tablet             | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                   | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------|--------|----------------------------------------|---------------------|
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Candesartancilexetil            | Candesartan Mylan 4 mg<br>comprimate                      | 4 mg   | Tablet                                 | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Candesartancilexetil            | Candesartan Mylan 8 mg<br>comprimate                      | 8 mg   | Tablet                                 | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Candesartancilexetil            | Candesartan Mylan 16<br>mg comprimate                     | 16 mg  | Tablet                                 | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Rizatriptanbenzoat              | Rizatriptan Mylan 5 mg<br>comprimate<br>orrodispersabile  | 5 mg   | Smeltetablet                           | Oral anvendelse     |
| Rumænien               | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Rizatriptanbenzoat              | Rizatriptan Mylan 10 mg<br>comprimate<br>orrodispersabile | 10 mg  | Smeltetablet                           | Oral anvendelse     |
| Rumænien               | Glenmark Pharmaceuticals<br>s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic   | Trimetazidin                    | Apstar 35mg<br>Comprimate cu<br>eliberare<br>prelungită   | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                               | Internationalt<br>generisk navn | Særnavn                                                                    | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------------------------------|--------|----------------------------------------|---------------------|
| Rumænien               | Labormed Pharma SA<br>Bd. Theodor Pallady nr. 44 B<br>032266, sector 3, București<br>România            | Desloratadin                    | Desloratadine Labormed<br>2.5 mg comprimate<br>orodispersabile             | 2,5 mg | Smeltetablet                           | Oral anvendelse     |
| Rumænien               | Labormed Pharma SA<br>Bd. Theodor Pallady nr. 44 B<br>032266, sector 3, București<br>România            | Desloratadin                    | Desloratadine Labormed<br>5 mg comprimate<br>orodispersabile               | 5 mg   | Smeltetablet                           | Oral anvendelse     |
| Rumænien               | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                                  | Trimetazidin                    | Trimetazidina Mylan 35<br>mg comprimate filmate<br>cu eliberare prelungita | 35 mg  | Depottablet                            | Oral anvendelse     |
| Rumænien               | Sandoz Pharma Services<br>SRL<br>Calea Floreasca Street<br>No 169A, district 2<br>Bucharest<br>Romania  | Trimetazidin                    | Trimeluzine Limited 35<br>mg comprimate filmate<br>cu eliberare modificata | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Rumænien               | STADA Hemofarm S.R.L.<br>Calea Torontalului km 6 -<br>PITT<br>300633 Timișoara<br>Romania               | Entacapon                       | ENTTANIDA 200<br>comprimate filmate                                        | 200 mg | Filmovertrukket<br>tablet              | Oral anvendelse     |
| Rumænien               | Teva Pharmaceuticals S.R.L.<br>Str. Domnița Ruxandra nr.<br>12, parter, sector 2,<br>București, România | Desloratadin                    | Desloratadina Teva 5 mg<br>comprimate<br>orodispersabile                   | 5 mg   | Smeltetablet                           | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                           | Internationalt<br>generisk navn   | Særnavn                                                                      | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Rumænien               | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan                        | Irbesartan Torrent 75 mg<br>comprimate<br>filmate                            | 75 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan                        | Irbesartan Torrent 150<br>mg comprimate<br>filmate                           | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan                        | Irbesartan Torrent 300<br>mg comprimate<br>filmate                           | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan/hydrochlorot<br>hiazid | Irbesartan Torrent<br>Hidrochlorotiazida<br>150/12,5mg comprimate<br>filmate | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Rumænien               | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan/hydrochlorot<br>hiazid | Irbesartan Torrent<br>Hidrochlorotiazida<br>300/12,5mg comprimate<br>filmate | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                           | Internationalt<br>generisk navn   | Særnavn                                                                     | Styrke          | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------------------------------------------------------------|-----------------|---------------------------|---------------------|
| Rumænien               | Torrent Pharma SRL<br>Str. Stirbei Voda nr. 36<br>et. 2, biroul A, sector 1<br>Bucharest<br>Romania | Irbesartan/hydrochlorot<br>hiazid | Irbesartan Torrent<br>Hidrochlorotiazida<br>300/25 mg comprimate<br>filmate | 300 mg/25<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Slovakiet              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                         | Cefpodoxim                        | FOREXO 200 mg filmom<br>obalené tablety                                     | 200 mg          | Filmovertrukket<br>tablet | Oral anvendelse     |
| Slovakiet              | Alvogen IPCo S.à.r.l.<br>Rue Heienhaff 5<br>1736 Senningerberg<br>Luxembourg                        | Desloratadin                      | Dezloratadin Alvogen 5<br>mg filmom obalené<br>tablety                      | 5 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Slovakiet              | Genericon s.r.o.,<br>Anny Letenské 1108/15,<br>120 00 Praha 2 - Vinohrady<br>Czech Republic         | Desloratadin                      | GESLORA 5 mg                                                                | 5 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Slovakiet              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom         | Donepezilhydrochlorid             | Donepezil Mylan 5 mg<br>orodispersgovateľné<br>tablety                      | 5 mg            | Smeltetablet              | Oral anvendelse     |
| Slovakiet              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom         | Donepezilhydrochlorid             | Donepezil Mylan 10 mg<br>orodispersgovateľné<br>tablety                     | 10 mg           | Smeltetablet              | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                     | Internationalt<br>generisk navn | Særnavn                                          | Styrke | Lægemiddelform                         | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------|--------|----------------------------------------|---------------------|
| Slovakiet              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom   | Rizatriptanbenzoat              | Rizatriptan Mylan 10 mg                          | 10 mg  | Smeltetablet                           | Oral anvendelse     |
| Slovakiet              | Glenmark Pharmaceuticals<br>s.r.o.<br>Hvězdova 1716/2b<br>14078 Praha 4<br>Czech Republic     | Trimetazidin                    | Apstar 35 mg tablety s<br>predíženým uvolňováním | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Slovakiet              | Mylan SAS<br>117 allée des Parcs<br>69792 Saint-Priest Cedex<br>France                        | Trimetazidin                    | Trimetazidin Mylan 35<br>mg                      | 35 mg  | Tablet med<br>modificeret<br>udløsning | Oral anvendelse     |
| Slovakiet              | SVUS Pharma a.s.<br>Smetanovo nábřeží<br>1238/20a<br>500 02 Hradec Králové<br>Czech Republic  | Desloratadin                    | LOTERA 5 mg filmom<br>obalené tablety            | 5 mg   | Filmovertrukket<br>tablet              | Oral anvendelse     |
| Slovakiet              | Teva Pharmaceuticals<br>Slovakia s.r.o.<br>Teslova 26<br>821 02 Bratislava<br>Slovak Republic | Desloratadin                    | Dezloratadin Teva<br>OROTAB 2,5 mg               | 2,5 mg | Smeltetablet                           | Oral anvendelse     |
| Slovakiet              | Teva Pharmaceuticals<br>Slovakia s.r.o.<br>Teslova 26<br>821 02 Bratislava<br>Slovak Republic | Desloratadin                    | Dezloratadin Teva<br>OROTAB 5 mg                 | 5 mg   | Smeltetablet                           | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn                                                      | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------|--------|---------------------------|---------------------|
| Slovenien              | Alkaloid - INT d.o.o.<br>Šlandrova 4<br>1231 Ljubljana - Črnuče<br>Slovenia                 | Cefpodoxim                      | Trexodo 200 mg filmsko<br>obložene tablete                   | 200 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Slovenien              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomeprazol Mylan 20<br>mg trde<br>gastrorezistentne kapsule | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Slovenien              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Esomeprazolmagnesium            | Esomeprazol Mylan 40<br>mg trde<br>gastrorezistentne kapsule | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Slovenien              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezilhydrochlorid           | Donepezil Mylan 5 mg<br>orodispersibilne tablete             | 5 mg   | Smeltetablet              | Oral anvendelse     |
| Slovenien              | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezilhydrochlorid           | Donepezil Mylan 10 mg<br>orodispersibilne tablete            | 10 mg  | Smeltetablet              | Oral anvendelse     |
| Slovenien              | Lek farmacevtska družba<br>d.d.<br>Verovškova 57<br>1526 Ljubljana<br>Slovenia              | Trimetazidinhydrochlorid        | Trimeluzine 35 mg<br>tablete s podaljšanim<br>sproščanjem    | 35 mg  | Depottablet               | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                   | Internationalt<br>generisk navn  | Særnavn                                                                                                      | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Spanien                | Accord Healthcare, S.L.U.<br>Moll de Barcelona s/n. World<br>Trade Center. Edifici Est 6 <sup>a</sup><br>planta,<br>8039 Barcelona<br>Spain | Metoclopramid                    | METOCLOPRAMIDA<br>ACCORD 10 MG<br>COMPRIMIDOS EFG                                                            | 10 mg             | Tablet                    | Oral anvendelse     |
| Spanien                | Apotex Europe B.V.<br>Darwinweg 20<br>NL 2333 CR Leiden<br>Netherlands                                                                      | Desloratadin                     | DES LorATADINA<br>APOTEX 5 mg<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG                              | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                                                | Ebastin                          | EBASTINA BROWN 10 MG<br>COMPRIMIDOS<br>BUCODISPERSABLES EFG                                                  | 10 mg             | Smeltetablet              | Oral anvendelse     |
| Spanien                | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                                                                  | Valsartan/hydrochlorothi<br>azid | VALSARTAN/HIDROCLOR<br>OTIAZIDA CODRAMOL<br>160 MG/12.5 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                                                                  | Valsartan/hydrochlorothi<br>azid | VALSARTAN/HIDROCLOR<br>OTIAZIDA CODRAMOL<br>160/25 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG      | 160 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                              | Internationalt<br>generisk navn  | Særnavn                                                                                                   | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Spanien                | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                             | Valsartan/hydrochlorothi<br>azid | VALSARTAN/HIDROCLOR<br>OTIAZIDA CODRAMOL<br>320/12.5 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                             | Valsartan/hydrochlorothi<br>azid | VALSARTAN/HIDROCLOR<br>OTIAZIDA CODRAMOL<br>320/25 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG   | 320 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Farmalider, S.A.<br>Aragoneses 15<br>28108 Madrid<br>Spain                                             | Valsartan/hydrochlorothi<br>azid | VALSARTAN/HIDROCLOR<br>OTIAZIDA CODRAMOL<br>80/12.5 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG  | 80 mg/12,5<br>mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Laboratorios Combix, S.L.U.<br>C/ Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Desloratadin                     | DESLORATADINA<br>COMBIX 5 mg<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELÍCULA EFG                            | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Laboratorios Combix, S.L.U.<br>C/ Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Desloratadin                     | DESLORATADINA FLAS<br>COMBIX 5 mg<br>COMPRIMIDOS<br>BUCODISPERSABLES EFG                                  | 5 mg              | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                              | Internationalt<br>generisk navn | Særnavn                                                                     | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------------------|--------|---------------------------|---------------------|
| Spanien                | Laboratorios Combix, S.L.U.<br>C/ Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Escitalopram                    | ESCITALOPRAM COMBIX<br>10 mg COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 10 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Laboratorios Combix, S.L.U.<br>C/ Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Escitalopram                    | ESCITALOPRAM COMBIX<br>15 mg COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 15 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Laboratorios Combix, S.L.U.<br>C/ Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Escitalopram                    | ESCITALOPRAM COMBIX<br>20 mg COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Laboratorios Combix, S.L.U.<br>C/ Badajoz 2, Edificio 2<br>Pozuelo de Alarcon<br>Madrid 28223<br>Spain | Escitalopram                    | ESCITALOPRAM COMBIX<br>5 mg COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG  | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Laboratorios Ranbaxy, S. L<br>U.<br>Paseig de Gracia 9<br>7a PI<br>Barcelona 08007<br>Spain            | Alendroninsyre                  | ACIDO ALENDRONICO<br>SEMANAL RANBAXY 70<br>mg COMPRIMIDOS EFG               | 70 mg  | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                     | Internationalt<br>generisk navn | Særnavn                                                                                  | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------------------------|--------|----------------|---------------------|
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain | Donepezil                       | DONEPEZILO FLAS<br>MYLAN<br>PHARMACEUTICALS 10<br>mg COMPRIMIDOS<br>BUCODISPERSABLES EFG | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain | Donepezil                       | DONEPEZILO FLAS<br>MYLAN<br>PHARMACEUTICALS 5 mg<br>COMPRIMIDOS<br>BUCODISPERSABLES EFG  | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain | Esomeprazol                     | ESOMEPRAZOL MYLAN 20<br>mg CAPSULAS<br>GASTRORRESISTENTES<br>EFG                         | 20 mg  | Enterokapsel   | Oral anvendelse     |
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain | Esomeprazol                     | ESOMEPRAZOL MYLAN 40<br>mg CAPSULAS<br>GASTRORRESISTENTES<br>EFG                         | 40 mg  | Enterokapsel   | Oral anvendelse     |
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain | Repaglinid                      | REPAGLINIDA MYLAN 0,5<br>MG COMPRIMIDOS EFG                                              | 0,5 mg | Tablet         | Oral anvendelse     |
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain | Repaglinid                      | REPAGLINIDA MYLAN 1<br>MG COMPRIMIDOS EFG                                                | 1 mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                   | Internationalt<br>generisk navn | Særnavn                                                                     | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------------------|--------|----------------|---------------------|
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain                               | Repaglinid                      | REPAGLINIDA MYLAN 2<br>MG COMPRIMIDOS EFG                                   | 2 mg   | Tablet         | Oral anvendelse     |
| Spanien                | Mylan Pharmaceuticals, S.L.<br>Plom 2-4, 5º Planta<br>8038 Barcelona<br>Spain                               | Rizatriptan                     | RIZATRIPTAN MAX<br>MYLAN 10 MG<br>COMPRIMIDOS<br>BUCODISPERSABLES EFG       | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Spanien                | PENSA PHARMA, S.A.U<br>Jorge Comín (médico<br>pediatra)<br>3 - bajos<br>46015– Valencia (Valencia)<br>Spain | Alendroninsyre                  | ACIDO ALENDRONICO<br>SEMANAL PENSA 70 mg<br>COMPRIMIDOS EFG                 | 70 mg  | Tablet         | Oral anvendelse     |
| Spanien                | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i<br>Plegamans (Barcelona)<br>Spain     | Desloratadin                    | DES LorATADINA<br>PHARMAGENUS 2,5 MG<br>COMPRIMIDOS<br>BUCODISPERSABLES EFG | 2,5 mg | Smeltetablet   | Oral anvendelse     |
| Spanien                | Pharmagenus, S.A.,<br>Avda. Camí Real, 51-57,<br>08184 Palau-solita i<br>Plegamans (Barcelona)<br>Spain     | Desloratadin                    | DES LorATADINA<br>PHARMAGENUS 5 MG<br>COMPRIMIDOS<br>BUCODISPERSABLES EFG   | 5 mg   | Smeltetablet   | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                             | Internationalt<br>generisk navn | Særnavn                                                                                                       | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Spanien                | Teva Pharma S.L.U.<br>C/ Anabel Segura, 11<br>Edificio Albatros B, 1ª planta<br>Madrid 28108<br>Spain | Desloratadin                    | DES LorATADINA TEVA 5<br>mg COMPRIMIDOS<br>BUCODISPERSABLES EFG                                               | 5 mg              | Smeltetablet              | Oral anvendelse     |
| Spanien                | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                   | Irbesartan                      | IRBESARTAN/HIDROCLO<br>ROTHIAZIDA WELDING<br>150 MG/12.5 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                   | Irbesartan                      | IRBESARTAN/HIDROCLO<br>ROTHIAZIDA WELDING<br>300 MG/12.5 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Spanien                | Welding GmbH & Co. KG<br>Esplanade 39<br>D-20354 Hamburg<br>Germany                                   | Irbesartan                      | IRBESARTAN/HIDROCLO<br>ROTHIAZIDA WELDING<br>300 MG/25 MG<br>COMPRIMIDOS<br>RECUBIERTOS CON<br>PELICULA EFG   | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                           | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------|--------|----------------|---------------------|
| Sverige                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | Alendronat Accord<br>Veckotablett | 70 mg  | Tablet         | Oral anvendelse     |
| Sverige                | Alternova A/S<br>Lodshusvej 11<br>DK-4230 Skælskør<br>Denmark                                                      | Clindamycinhydrochlorid         | Clindamycin Alternova             | 150 mg | Kapsel, hård   | Oral anvendelse     |
| Sverige                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                        | Fluconazol                      | Fluconazol Bluefish               | 50 mg  | Kapsel, hård   | Oral anvendelse     |
| Sverige                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                        | Fluconazol                      | Fluconazol Bluefish               | 150 mg | Kapsel, hård   | Oral anvendelse     |
| Sverige                | Bluefish Pharmaceuticals AB<br>Torsgatan 11<br>SE-11123 Stockholm<br>Sweden                                        | Fluconazol                      | Fluconazol Bluefish               | 200 mg | Kapsel, hård   | Oral anvendelse     |
| Sverige                | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                        | Donepezilhydrochlorid           | Donezil                           | 5 mg   | Smeltetablet   | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                   | Internationalt<br>generisk navn | Særnavn           | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------|---------------------------------|-------------------|--------|----------------|---------------------|
| Sverige                | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom | Donepezilhydrochlorid           | Donezil           | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Donepezil                       | Donepezil Mylan   | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Donepezil                       | Donepezil Mylan   | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Rizatriptan                     | Rizatriptan Mylan | 10 mg  | Smeltetablet   | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Repaglinid                      | Repaglinid Mylan  | 0,5 mg | Tablet         | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Repaglinid                      | Repaglinid Mylan  | 1 mg   | Tablet         | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden                                  | Repaglinid                      | Repaglinid Mylan  | 2 mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                | Internationalt<br>generisk navn | Særnavn           | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------|---------------------------------|-------------------|--------|---------------------------|---------------------|
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Esomeprazol                     | Esomeprazol Mylan | 20 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Esomeprazol                     | Esomeprazol Mylan | 40 mg  | Enterokapsel, hård        | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Eletriptan                      | Eletriptan Mylan  | 20 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Sverige                | Mylan AB<br>PO Box 230 33<br>SE-104 35 Stockholm<br>Sweden               | Eletriptan                      | Eletriptan Mylan  | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Sverige                | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan                       | Valsartan Orion   | 40 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Sverige                | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland | Valsartan                       | Valsartan Orion   | 80 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                               | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------------|--------|---------------------------|---------------------|
| Sverige                | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                           | Valsartan                       | Valsartan Orion                                       | 160 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Sverige                | Orion Corporation<br>Orion Pharma<br>PO BOX 65<br>02101 Espoo<br>Finland                                           | Valsartan                       | Valsartan Orion                                       | 320 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Sverige                | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom         | Alendroninsyre                  | Alendronat Ranbaxy<br>Veckotablett 70 mg<br>tabletter | 70 mg  | Tablet                    | Oral anvendelse     |
| Sverige                | Stada Arzneimittel AG<br>Stadastrasse 2-18<br>DE-61118 Bad Vilbel<br>Germany                                       | Entacapon                       | Entakapon STADA                                       | 200 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirol Accord 5 mg,<br>filmomhulde tabletten       | 5 mg   | Filmovertrukket<br>tablet | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                  | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                    | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------|-----------------------------------------|---------------------------------------------------|---------------|---------------------------|----------------------------|
| Holland                        | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                               | Ropinirol Accord 0,25 mg<br>filmomhulde tabletten | 0,25 mg       | Filmovertrukket<br>tablet | Oral anvendelse            |
| Holland                        | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                               | Ropinirol Accord 0,5 mg<br>filmomhulde tabletten  | 0,5 mg        | Filmovertrukket<br>tablet | Oral anvendelse            |
| Holland                        | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                               | Ropinirol Accord 1 mg<br>filmomhulde tabletten    | 1 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |
| Holland                        | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                               | Ropinirol Accord 2 mg<br>filmomhulde tabletten    | 2 mg          | Filmovertrukket<br>tablet | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                               | Internationalt<br>generisk navn | Særnavn                                                                              | Styrke  | Lægemiddelform    | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------------------------------------------------------|---------|-------------------|---------------------|
| Holland                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom      | Alendroninsyre                  | Alendroninezuur Accord<br>10mg Tabletten                                             | 10 mg   | Tablet            | Oral anvendelse     |
| Holland                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom      | Alendroninsyre                  | Alendroninezuur Accord<br>70mg Tabletten                                             | 70 mg   | Tablet            | Oral anvendelse     |
| Holland                | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom      | Metoclopramidhydrochlorid       | Metoclopramidemonohydrochloride Accord 10 mg,<br>Tabletten                           | 10 mg   | Tablet            | Oral anvendelse     |
| Holland                | Alembic Pharmaceuticals<br>Europe Limited<br>Palazzo Pietro Stiges, 103,<br>Strait Street<br>VLT 1436 Valletta<br>Malta | Venlafaxin                      | Venlafaxine HCl Retard<br>Alembic 37,5 mg, capsule<br>met verlengde afgifte,<br>hard | 37,5 mg | Depotkapsel, hård | Oral anvendelse     |

| <b>Medlemsland<br/>(i EØS)</b> | <b>Indehaver af<br/>markedsføringstilladelsen</b>                                                                       | <b>Internationalt<br/>generisk navn</b> | <b>Særnavn</b>                                                                      | <b>Styrke</b> | <b>Lægemiddelform</b>     | <b>Administrationsmåde</b> |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------------------------------|---------------|---------------------------|----------------------------|
| Holland                        | Alembic Pharmaceuticals<br>Europe Limited<br>Palazzo Pietro Stiges, 103,<br>Strait Street<br>VLT 1436 Valletta<br>Malta | Venlafaxin                              | Venlafaxine HCl Retard<br>Alembic 75 mg, capsule<br>met verlengde afgifte,<br>hard  | 75 mg         | Depotkapsel, hård         | Oral anvendelse            |
| Holland                        | Alembic Pharmaceuticals<br>Europe Limited<br>Palazzo Pietro Stiges, 103,<br>Strait Street<br>VLT 1436 Valletta<br>Malta | Venlafaxin                              | Venlafaxine HCl Retard<br>Alembic 150 mg, capsule<br>met verlengde afgifte,<br>hard | 150 mg        | Depotkapsel, hård         | Oral anvendelse            |
| Holland                        | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                            | Ebastin                                 | Ebastine BB 10 mg<br>orodispergeerbare<br>tabletten                                 | 10 mg         | Smeltetablet              | Oral anvendelse            |
| Holland                        | Centrafarm B.V.<br>Nieuwe Donk 3<br>4879 AC Etten Leur<br>The Netherlands                                               | Entacapon                               | Entacapone CF 200 mg,<br>filmomhulde tablet                                         | 200 mg        | Filmovertrukket<br>tablet | Oral anvendelse            |
| Holland                        | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                             | Ciprofloxacin                           | Ciprofloxacin Fair-Med<br>250 mg, filmomhulde<br>tabletten                          | 250 mg        | Filmovertrukket<br>tablet | Oral anvendelse            |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn  | Særnavn                                                                 | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|----------------------------------|-------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                    | Ciprofloxacin Fair-Med<br>500 mg, filmomhulde<br>tabletten              | 500 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Ciprofloxacin                    | Ciprofloxacin Fair-Med<br>750 mg, filmomhulde<br>tabletten              | 750 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/HCTZ Fair-Med<br>160 mg/12,5 mg,<br>filmomhulde tabletten     | 160 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/HCTZ Fair-Med<br>320 mg/12,5 mg,<br>filmomhulde tabletten     | 320 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Valsartan/hydrochlorothi<br>azid | Valsartan/HCTZ Fair-Med<br>320 mg/25 mg,<br>filmomhulde tabletten       | 320 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaxin                       | Venlafaxine Fair-Med<br>37,5 mg capsules met<br>verlengde afgifte, hard | 37,5 mg           | Depotkapsel, hård         | Oral anvendelse     |
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Venlafaxin                       | Venlafaxine Fair-Med 75<br>mg capsules met<br>verlengde afgifte, hard   | 75 mg             | Depotkapsel, hård         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                  | Internationalt<br>generisk navn | Særnavn                                                                | Styrke | Lægemiddelform     | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------------------------------------|--------|--------------------|---------------------|
| Holland                | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany                                | Venlafaxin                      | Venlafaxine Fair-Med 150<br>mg capsules met<br>verlengde afgifte, hard | 150 mg | Depotkapsel, hård  | Oral anvendelse     |
| Holland                | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Esomeprazol                     | Esomeprazol Mylan 20<br>mg, maagsapresistente<br>capsules, hard        | 20 mg  | Enterokapsel, hård | Oral anvendelse     |
| Holland                | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Esomeprazol                     | Esomeprazol Mylan 40<br>mg, maagsapresistente<br>capsules, hard        | 40 mg  | Enterokapsel, hård | Oral anvendelse     |
| Holland                | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Rizatriptan                     | Rizatriptan SmeltTab<br>Mylan 5 mg,<br>orodispergeerbare<br>tabletten  | 5 mg   | Smeltetablet       | Oral anvendelse     |
| Holland                | Mylan B.V.<br>Dieselweg 25<br>3752 LB Bunschoten<br>The Netherlands                                        | Rizatriptan                     | Rizatriptan SmeltTab<br>Mylan 10 mg,<br>orodispergeerbare<br>tabletten | 10 mg  | Smeltetablet       | Oral anvendelse     |
| Holland                | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom | Alendroninsyre                  | Alendroninezuur 70<br>Ranbaxy, tabletten 70<br>mg                      | 70 mg  | Tablet             | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                     | Internationalt<br>generisk navn | Særnavn                                                                     | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------------------|--------|----------------|---------------------|
| Holland                | Sandoz B.V.<br>Veluwezoom 22<br>1327 AH Almere<br>The Netherlands                             | Clonazepam                      | Clonazepam Sandoz 0,5<br>mg, tabletten                                      | 0,5 mg | Tablet         | Oral anvendelse     |
| Holland                | Sandoz B.V.<br>Veluwezoom 22<br>1327 AH Almere<br>The Netherlands                             | Clonazepam                      | Clonazepam Sandoz 2<br>mg, tabletten                                        | 2 mg   | Tablet         | Oral anvendelse     |
| Holland                | Sandoz B.V.<br>Veluwezoom 22<br>1327 AH Almere<br>The Netherlands                             | Clobazam                        | Clobazam Sandoz 10 mg,<br>tabletten                                         | 10 mg  | Tablet         | Oral anvendelse     |
| Holland                | Teva Nederland B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                       | Desloratadin                    | Desloratadine<br>Smelttablet 2,5 mg Teva,<br>orodispergeerbare<br>tabletten | 2,5 mg | Smelttablet    | Oral anvendelse     |
| Holland                | Teva Nederland B.V.<br>Swensweg 5<br>2031 GA Haarlem<br>The Netherlands                       | Desloratadin                    | Desloratadine<br>Smelttablet 5 mg Teva,<br>orodispergeerbare<br>tabletten   | 5 mg   | Smelttablet    | Oral anvendelse     |
| Holland                | TioFarma b.v.<br>Benjamin Franklinstraat 5-<br>10<br>3261 LW Oud-Beyerland<br>The Netherlands | Clonazepam                      | Clonazepam TioFarma<br>0,5 mg tabletten,<br>tabletten                       | 0,5 mg | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                 | Internationalt<br>generisk navn | Særnavn                                         | Styrke | Lægemiddelform         | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------|--------|------------------------|---------------------|
| Holland                | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Clonazepam                      | Clonazepam TioFarma 2 mg tabletten, tabletten   | 2 mg   | Tablet                 | Oral anvendelse     |
| Holland                | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Clobazam                        | Clobazam TioFarma 10 mg, tabletten              | 10 mg  | Tablet                 | Oral anvendelse     |
| Holland                | TioFarma b.v.<br>Benjamin Franklinstraat 5-10<br>3261 LW Oud-Beyerland<br>The Netherlands | Clobazam                        | Clobazam TioFarma 20 mg, tabletten              | 20 mg  | Tablet                 | Oral anvendelse     |
| Holland                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | irbesartan                      | Irbesartan Torrent 75 mg filmomhulde tabletten  | 75 mg  | Filmovertrukket tablet | Oral anvendelse     |
| Holland                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | irbesartan                      | Irbesartan Torrent 150 mg filmomhulde tabletten | 150 mg | Filmovertrukket tablet | Oral anvendelse     |
| Holland                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                        | irbesartan                      | Irbesartan Torrent 300 mg filmomhulde tabletten | 300 mg | Filmovertrukket tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                                                    | Internationalt<br>generisk navn   | Særnavn                                                                              | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|--------------------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Holland                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                                                           | Irbesartan/hydrochlorot<br>hiazid | Irbesartan<br>Hydrochloorthiazide<br>Torrent 150 mg/12,5 mg<br>filmomhulde tabletten | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                                                           | Irbesartan/hydrochlorot<br>hiazid | Irbesartan<br>Hydrochloorthiazide<br>Torrent 300 mg/12,5 mg<br>filmomhulde tabletten | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany                                                                           | Irbesartan/hydrochlorot<br>hiazid | Irbesartan<br>Hydrochloorthiazide<br>Torrent 300 mg/25 mg<br>filmomhulde tabletten   | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe<br>Commercial Centre,<br>Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | irbesartan                        | Irbesartan Unichem 150<br>mg filmomhulde tabletten                                   | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Holland                | Unichem Laboratories Ltd.<br>Studio 8B Ard Gaoithe<br>Commercial Centre,<br>Business Park<br>Cashel Road Clonmel,<br>Co Tipperary<br>Ireland | irbesartan                        | Irbesartan Unichem 300<br>mg filmomhulde tabletten                                   | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                   | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------|---------|---------------------------|---------------------|
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole 0.25mg film-<br>coated tablets | 0,25 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole 0.5mg film-<br>coated tablets  | 0,5 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole 1mg film-<br>coated tablets    | 1 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole 2mg film-<br>coated tablets    | 2 mg    | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                         | Styrke | Lægemiddelform             | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------------|--------|----------------------------|---------------------|
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | alendronic acid 10mg<br>Tablets                 | 10 mg  | Tablet                     | Oral anvendelse     |
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Alendroninsyre                  | alendronic acid 70mg<br>Once Daily Tablets      | 70 mg  | Tablet                     | Oral anvendelse     |
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Metoclopramidhydrochlorid       | metoclopramide<br>hydrochloride 10mg<br>tablets | 10 mg  | Tablet                     | Oral anvendelse     |
| Storbritannien         | Accord Healthcare Limited<br>Sage House, 319 Pinner<br>Road<br>North Harrow HA1 4HF<br>Middlesex<br>United Kingdom | Ropinirol                       | Ropinirole 5mg film-<br>coated tablets          | 5 mg   | Filmoverttrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                               | Internationalt<br>generisk navn | Særnavn                       | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------|--------|----------------|---------------------|
| Storbritannien         | Aptil Pharma Limited<br>9th Floor, CP House<br>97-107 Uxbridge Road<br>London W5 5TL<br>United Kingdom  | Fluconazol                      | Fluconazole 50mg<br>capsules  | 50 mg  | Kapsel, hård   | Oral anvendelse     |
| Storbritannien         | Aptil Pharma Limited<br>9th Floor, CP House<br>97-107 Uxbridge Road<br>London W5 5TL<br>United Kingdom  | Fluconazol                      | Fluconazole 150mg<br>capsules | 150 mg | Kapsel, hård   | Oral anvendelse     |
| Storbritannien         | Aptil Pharma Limited<br>9th Floor, CP House<br>97-107 Uxbridge Road<br>London W5 5TL<br>United Kingdom  | Fluconazol                      | Fluconazole 200mg<br>capsules | 200 mg | Kapsel, hård   | Oral anvendelse     |
| Storbritannien         | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Dexamethason                    | Dexamethasone 2mg<br>Tablets  | 2 mg   | Tablet         | Oral anvendelse     |
| Storbritannien         | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Thiaminhydrochlorid             | Tyvera 50mg Tablets           | 50 mg  | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                               | Internationalt<br>generisk navn | Særnavn                                                 | Styrke | Lægemiddelform             | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------------|--------|----------------------------|---------------------|
| Storbritannien         | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Thiaminhydrochlorid             | Tyvera 100mg Tablets                                    | 100 mg | Tablet                     | Oral anvendelse     |
| Storbritannien         | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Clonazepam                      | Clonazepam 500mcg<br>Tablet                             | 0,5 mg | Tablet                     | Oral anvendelse     |
| Storbritannien         | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Clonazepam                      | Clonazepam 2mg Tablet                                   | 2 mg   | Tablet                     | Oral anvendelse     |
| Storbritannien         | Auden McKenzie Limited<br>McKenzie House<br>Bury Street, Ruislip<br>Middlesex HA4 7TL<br>United Kingdom | Clobazam                        | CLOBAZAM AUDEN 10mg<br>TABLETS                          | 10 mg  | Tablet                     | Oral anvendelse     |
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom            | Phenoxymethylpenicillin         | Phenoxymethylpenicillin<br>250mg Film-coated<br>Tablets | 250 mg | Filmoverttrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                    | Internationalt<br>generisk navn | Særnavn                               | Styrke | Lægemiddelform         | Administrationsmåde |
|------------------------|----------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------|--------|------------------------|---------------------|
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopramoxalat              | Escitalopram 5mg Film-coated tablets  | 5 mg   | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopramoxalat              | Escitalopram 10mg Film-coated tablets | 10 mg  | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopramoxalat              | Escitalopram 15mg Film-coated tablets | 15 mg  | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Escitalopramoxalat              | Escitalopram 20mg Film-coated tablets | 20 mg  | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom | Tramadolhydrochlorid            | Aceon 100mg Prolonged-release tablets | 100 mg | Depottablet            | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                   | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------|--------|----------------|---------------------|
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                       | Tramadolhydrochlorid            | Aceon 150mg Prolonged-<br>release tablets | 150 mg | Depottablet    | Oral anvendelse     |
| Storbritannien         | Brown & Burk UK, Ltd.<br>5, Marryat Close<br>Hounslow<br>TW4 5DQ Middlesex<br>United Kingdom                       | Tramadolhydrochlorid            | Aceon 200mg Prolonged-<br>release tablets | 200 mg | Depottablet    | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan                       | Valsartan 40mg Capsules                   | 40 mg  | Kapsel         | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan                       | Valsartan 80mg Capsules                   | 80 mg  | Kapsel         | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan                       | Valsartan 160mg<br>Capsules               | 160 mg | Kapsel         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                     | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------|---------|---------------------------|---------------------|
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Valsartan                       | Valsartan 320mg<br>Capsules                 | 320 mg  | Kapsel                    | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam                   | Levetiracetam 250mg<br>film-coated tablets  | 250 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam                   | Levetiracetam 500mg<br>film-coated tablets  | 500 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam                   | Levetiracetam 750mg<br>film-coated tablets  | 750 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Levetiracetam                   | Levetiracetam 1000mg<br>film-coated tablets | 1000 mg | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn | Særnavn                                  | Styrke | Lægemiddelform                               | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------------|--------|----------------------------------------------|---------------------|
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Pioglitazon                     | Pioglitazone 15mg<br>Tablets             | 15 mg  | Tablet                                       | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Pioglitazon                     | Pioglitazone 30mg<br>Tablets             | 30 mg  | Tablet                                       | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Pioglitazon                     | Pioglitazone 45mg<br>Tablets             | 45 mg  | Tablet                                       | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Dipyridamol                     | Attia 200mg Modified<br>Release Capsules | 200 mg | Kapsel med<br>modificeret<br>udløsning, hård | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan                     | Telmisartan 20mg<br>Tablets              | 20 mg  | Tablet                                       | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                          | Internationalt<br>generisk navn    | Særnavn                                                    | Styrke           | Lægemiddelform | Administrationsmåde |
|------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------------------------------|------------------|----------------|---------------------|
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan                        | Telmisartan 40mg<br>Tablets                                | 40 mg            | Tablet         | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan                        | Telmisartan 80mg<br>Tablets                                | 80 mg            | Tablet         | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan/hydrochloro<br>thiazid | Telmisartan/Hydrochlorot<br>hiazide 40mg/12.5mg<br>Tablets | 40 mg/12,5<br>mg | Tablet         | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan/hydrochloro<br>thiazid | Telmisartan/Hydrochlorot<br>hiazide 80mg/12.5mg<br>Tablets | 80 mg/12,5<br>mg | Tablet         | Oral anvendelse     |
| Storbritannien         | Dr Reddy's Laboratories<br>(UK) Limited<br>6 Riverview Road, Beverley<br>East Yorkshire HU17 0LD<br>United Kingdom | Telmisartan/hydrochloro<br>thiazid | Telmisartan/Hydrochlorot<br>hiazide 80mg/25mg<br>Tablets   | 80 mg/25<br>mg   | Tablet         | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                   | Internationalt<br>generisk navn | Særnavn                                                         | Styrke         | Lægemiddelform         | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------------|----------------|------------------------|---------------------|
| Storbritannien         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                      | Irbesartan 75mg Film-coated Tablets                             | 75 mg          | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                      | Irbesartan 150mg Film-coated Tablets                            | 150 mg         | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | irbesartan                      | Irbesartan 300mg Film-coated Tablets                            | 300 mg         | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorothiazid   | Irbesartan/Hydrochlorothiazide 150mg/12.5mg film-coated tablets | 150 mg/12,5 mg | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorothiazid   | Irbesartan/Hydrochlorothiazide 300mg/12.5mg film-coated tablets | 300 mg/12,5 mg | Filmovertrukket tablet | Oral anvendelse     |
| Storbritannien         | Fair-Med Healthcare GmbH<br>Planckstrasse 13<br>DE-22765 Hamburg<br>Germany | Irbesartan/hydrochlorothiazid   | Irbesartan/Hydrochlorothiazide 300mg/25mg film-coated tablets   | 300 mg/25 mg   | Filmovertrukket tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                               | Internationalt<br>generisk navn | Særnavn                                   | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------------------------------------------|--------|---------------------------|---------------------|
| Storbritannien         | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Fluconazol                      | Fluconazole 150mg<br>capsule              | 150 mg | Kapsel, hård              | Oral anvendelse     |
| Storbritannien         | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Fexofenadin                     | Fexofenadine 120mg<br>film-coated tablets | 120 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Fannin (UK) Ltd<br>42-46 Booth Drive<br>Park Farm South<br>Wellingborough<br>Northamptonshire NN8 6GT<br>United Kingdom | Fexofenadin                     | Fexofenadine 180mg<br>film-coated tablets | 180 mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | FDC Pharma<br>Unit 6, Fulcrum 1, Solent<br>Way<br>Whiteley, Fareham<br>Hampshire PO15 7FE<br>United Kingdom             | Amlodipin                       | Amlodipine 5mg Tablets                    | 5 mg   | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                   | Internationalt<br>generisk navn | Særnavn                                                  | Styrke | Lægemiddelform | Administrationsmåde |
|------------------------|-------------------------------------------------------------------------------------------------------------|---------------------------------|----------------------------------------------------------|--------|----------------|---------------------|
| Storbritannien         | FDC Pharma<br>Unit 6, Fulcrum 1, Solent<br>Way<br>Whiteley, Fareham<br>Hampshire PO15 7FE<br>United Kingdom | Amlodipin                       | Amlodipine 10mg Tablets                                  | 10 mg  | Tablet         | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                 | Repaglinid                      | Repaglinide Mylan 0.5mg<br>Tablets                       | 0,5 mg | Tablet         | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                 | Repaglinid                      | Repaglinide Mylan 1mg<br>Tablets                         | 1 mg   | Tablet         | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                 | Repaglinid                      | Repaglinide Mylan 2mg<br>Tablets                         | 2 mg   | Tablet         | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                 | Donepezilhydrochlorid           | Donepezil Hydrochloride<br>5mg Orodispersible<br>Tables  | 5 mg   | Smeltetablet   | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                 | Donepezilhydrochlorid           | Donepezil Hydrochloride<br>10mg Orodispersible<br>Tables | 10 mg  | Smeltetablet   | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                  | Internationalt<br>generisk navn  | Særnavn                                                                 | Styrke                   | Lægemiddelform             | Administrationsmåde |
|------------------------|------------------------------------------------------------------------------------------------------------|----------------------------------|-------------------------------------------------------------------------|--------------------------|----------------------------|---------------------|
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                | Rizatriptanbenzoat               | Rizatriptan 10mg<br>Orodispersible Tablet                               | 10 mg                    | Smeltetablet               | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                | Esomeprazolmagnesium             | Esomeprazole 20mg<br>Gastro-resistant<br>Capsules, hard                 | 20 mg                    | Enterokapsel               | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                | Esomeprazolmagnesium             | Esomeprazole 40mg<br>Gastro-resistant<br>Capsules, hard                 | 40 mg                    | Enterokapsel               | Oral anvendelse     |
| Storbritannien         | Generics (UK) Ltd<br>Station Close, Potters Bar<br>Hertfordshire, EN6 1TL<br>United Kingdom                | Levodopa/carbidopa/ent<br>acapon | Levodopa/Carbidopa/Enta<br>capone film-coated<br>tablets 150/37.5/200mg | 150 mg/37,5<br>mg/200 mg | Filmoverttrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16<br>0PF<br>United Kingdom | Pantoprazol                      | Pantoprazole 20mg<br>Gastro-Resistant tablets                           | 20 mg                    | Enterotablet               | Oral anvendelse     |
| Storbritannien         | Lupin (Europe) Limited<br>Victoria Court, Bexton Road<br>Knutsford, Cheshire WA16<br>0PF<br>United Kingdom | Pantoprazol                      | Pantoprazole 40mg<br>Gastro-Resistant tablets                           | 40 mg                    | Enterotablet               | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                     | Internationalt<br>generisk navn | Særnavn                                                   | Styrke  | Lægemiddelform            | Administrationsmåde |
|------------------------|---------------------------------------------------------------------------------------------------------------|---------------------------------|-----------------------------------------------------------|---------|---------------------------|---------------------|
| Storbritannien         | Morningside Healthcare<br>Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom              | Phenoxymethylpenicillin         | Phenoxymethylpenicillin<br>250mg Film-coated<br>Tablets   | 250 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Morningside Healthcare<br>Limited<br>115 Narborough Road<br>Leicester, LE3 0PA<br>United Kingdom              | Metforminhydrochlorid           | Bolamyn/Metabet SR<br>1000mg Prolonged<br>Release Tablets | 1000 mg | Depottablet               | Oral anvendelse     |
| Storbritannien         | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | irbesartan                      | Irbesartan Niche 150mg<br>film-coated tablets             | 150 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Niche Generics Limited<br>1 The Cam Centre<br>Wilbury Way, Hitchin<br>Hertfordshire SG4 0TW<br>United Kingdom | irbesartan                      | Irbesartan Niche 150mg<br>film-coated tablets             | 150 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Ranbaxy UK Ltd.<br>Building 4, Chiswick Park<br>566 Chiswick High Road<br>London, W4 5YE<br>United Kingdom    | Alendroninsyre                  | Alendronic Acid 70mg<br>Tablets                           | 70 mg   | Tablet                    | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                          | Internationalt<br>generisk navn   | Særnavn                                                                   | Styrke            | Lægemiddelform            | Administrationsmåde |
|------------------------|--------------------------------------------------------------------|-----------------------------------|---------------------------------------------------------------------------|-------------------|---------------------------|---------------------|
| Storbritannien         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan<br>Hydrochlorothiazide<br>150mg/12.5mg Film-<br>coated tablets | 150 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan<br>Hydrochlorothiazide<br>300mg/12.5mg Film-<br>coated tablets | 300 mg/12,5<br>mg | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | Irbesartan/hydrochlorot<br>hiazid | Irbesartan<br>Hydrochlorothiazide<br>300mg/25mg Film-<br>coated tablets   | 300 mg/25<br>mg   | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | irbesartan                        | Irbesartan 75mg Film-<br>coated tablets                                   | 75 mg             | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | irbesartan                        | Irbesartan 150mg Film-<br>coated tablets                                  | 150 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | Torrent Pharma GmbH<br>Südwestpark 50<br>90449 Nürnberg<br>Germany | irbesartan                        | Irbesartan 300mg Film-<br>coated tablets                                  | 300 mg            | Filmovertrukket<br>tablet | Oral anvendelse     |

| Medlemsland<br>(i EØS) | Indehaver af<br>markedsføringstilladelsen                                                                 | Internationalt<br>generisk navn | Særnavn                                           | Styrke | Lægemiddelform            | Administrationsmåde |
|------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------------|---------------------------------------------------|--------|---------------------------|---------------------|
| Storbritannien         | Waymade PLC<br>Sovereign House<br>Miles Grat Road, Basildon<br>Essex SS14 3FR<br>United Kingdom           | Venlafaxinhydrochlorid          | Venlasov XL 75mg<br>Modified Release<br>Capsules  | 75 mg  | Depotkapsel, hård         | Oral anvendelse     |
| Storbritannien         | Waymade PLC<br>Sovereign House<br>Miles Grat Road, Basildon<br>Essex SS14 3FR<br>United Kingdom           | Venlafaxinhydrochlorid          | Venlasov XL 150mg<br>Modified Release<br>Capsules | 150 mg | Depotkapsel, hård         | Oral anvendelse     |
| Storbritannien         | Wockhardt UK Limited<br>Ash Road North<br>Wrexham Industrial Estate<br>Wrexham LL13 9UF<br>United Kingdom | Clopidogrel                     | Clopidogrel 75mg Film-<br>coated Tablets          | 75 mg  | Filmovertrukket<br>tablet | Oral anvendelse     |
| Storbritannien         | YJBPort Limited<br>74 Briarwood Drive<br>Northwood Hills<br>Middlesex HA6 1PL<br>United Kingdom           | Hydrocortison                   | Hydrocortisone 10mg<br>Tablets                    | 10 mg  | Tablet                    | Oral anvendelse     |
| Storbritannien         | YJBPort Limited<br>74 Briarwood Drive<br>Northwood Hills<br>Middlesex HA6 1PL<br>United Kingdom           | Hydrocortison                   | Hydrocortisone 20mg<br>Tablets                    | 20 mg  | Tablet                    | Oral anvendelse     |