



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

29 September 2016  
EMA/662266/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance(s): amlodipine / atorvastatine

Procedure No.: PSUSA/00000177/201601



| Product Name (in authorisation country) | MRP / DCP Authorisation number                                | National Authorisation Number                                                                                                                                                                                                                                                                                 | MAH of product in the member state  | Member State where product is authorised |
|-----------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|------------------------------------------|
| Amaloris                                | SI/H/0142/002                                                 | H/13/0158/011                                                                                                                                                                                                                                                                                                 | Krka, D.D., Novo Mesto              | Slovenia                                 |
| Amaloris                                | SI/H/0142/002 & SI/H/0142/003                                 | 811513 & 845714                                                                                                                                                                                                                                                                                               | Krka, D.D., Novo Mesto              | Estonia                                  |
| Amaloris                                | SI/H/0142/002 & SI/H/0142/003                                 | H/13/0158/001 & H/13/0158/002 & H/13/0158/003 & H/13/0158/004 & H/13/0158/005 & H/13/0158/006 & H/13/0158/007 & H/13/0158/008 & H/13/0158/009 & H/13/0158/010 & H/13/0158/012 & H/13/0158/013 & H/13/0158/014 & H/13/0158/015 & H/13/0158/016 & H/13/0158/017 & H/13/0158/018 & H/13/0158/019 & H/13/0158/020 | Krka, D.D., Novo Mesto              | Slovenia                                 |
| Amlator                                 | HU/H/0248/001                                                 | 58/480/11-C                                                                                                                                                                                                                                                                                                   | Gedeon Richter Plc.                 | Czech Republic                           |
| Amlator                                 | HU/H/0248/001 & HU/H/0248/002 & HU/H/0248/003 & HU/H/0248/004 | 18573 & 18574 & 18575 & 18576                                                                                                                                                                                                                                                                                 | Gedeon Richter Plc.                 | Poland                                   |
| Amlator                                 | HU/H/0248/001 & HU/H/0248/002 & HU/H/0248/003 & HU/H/0248/004 | OGYI-T-21844/01 & OGYI-T-21844/02 & OGYI-T-21844/03 & OGYI-T-21844/04                                                                                                                                                                                                                                         | Gedeon Richter Plc.                 | Hungary                                  |
| Amlator                                 | HU/H/0248/001 & HU/H/0248/003                                 | 58/0381/11-S & 58/0383/11-S                                                                                                                                                                                                                                                                                   | Gedeon Richter Plc.                 | Slovakia                                 |
| Amlator                                 | HU/H/0248/002 & HU/H/0248/003 & HU/H/0248/004                 | 58/481/11-C & 58/482/11-C & 58/483/11-C                                                                                                                                                                                                                                                                       | Gedeon Richter Plc.                 | Czech Republic                           |
| Amlator                                 | HU/H/0248/002 & HU/H/0248/004                                 | 58/0382/11-S & 58/0384/11-S                                                                                                                                                                                                                                                                                   | Gedeon Richter Plc.                 | Slovakia                                 |
| Amloat                                  | PT/H/1082/001                                                 | 58/0244/14-S                                                                                                                                                                                                                                                                                                  | Teva Pharmaceuticals Slovakia S.R.O | Slovakia                                 |
| Amloat                                  | PT/H/1082/002                                                 | 58/0245/14-S                                                                                                                                                                                                                                                                                                  | Teva Pharmaceuticals Slovakia S.R.O | Slovakia                                 |
| Amlodipin / Atorvastatin Actavis        | PT/H/0841/002                                                 | 83/214/13-C                                                                                                                                                                                                                                                                                                   | Actavis Group Ptc Ehf.              | Czech Republic                           |
| Amlodipin/Atorvastatin Actavis          | PT/H/0841/001                                                 | 83/213/13-C                                                                                                                                                                                                                                                                                                   | Actavis Group Ptc Ehf.              | Czech Republic                           |
| Amlodipin/Atorvastatin Krka             | SI/H/0143/002                                                 | H/13/00177/001                                                                                                                                                                                                                                                                                                | Krka, D.D., Novo Mesto              | Slovenia                                 |
| Amlodipin/Atorvastatin Krka             | SI/H/0143/002 & SI/H/0143/003                                 | 58/0092/13-S & 58/0147/14-S                                                                                                                                                                                                                                                                                   | Krka, D.D., Novo Mesto              | Slovakia                                 |
| Amlodipin/Atorvastatin Krka             | SI/H/0143/002 & SI/H/0143/003                                 | OGYI-T-22436/01 & OGYI-T-22436/02 & OGYI-T-22436/03 & OGYI-T-22436/04 & OGYI-T-22436/05 & OGYI-T-22436/06 & OGYI-T-22436/07 & OGYI-T-22436/08 &                                                                                                                                                               | Krka, D.D., Novo Mesto              | Hungary                                  |

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|-----------------------------------------|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|------------------------------------------|
|                                         |                                                  | OGYI-T-22436/09 & OGYI-T-22436/10                                                                                                                                                                                                                                                                                                |                                                               |                                          |
| Amlodipin/Atorvastatin Krka             | SI/H/0143/002 & SI/H/0143/003 & SI/H/0143/003/DC | H/13/00177/002 & H/13/00177/003 & H/13/00177/004 & H/13/00177/005 & H/13/00177/006 & H/13/00177/007 & H/13/00177/008 & H/13/00177/009 & H/13/00177/010 & H/13/00177/011 & H/13/00177/012 & H/13/00177/013 & H/13/00177/014 & H/13/00177/015 & H/13/00177/016 & H/13/00177/017 & H/13/00177/018 & H/13/00177/019 & H/13/00177/020 | Krka, D.D., Novo Mesto                                        | Slovenia                                 |
| Amlodipin/Atorvastatin Teva             | PT/H/1082/001                                    | 83/302/14-C                                                                                                                                                                                                                                                                                                                      | Teva Pharmaceuticals Cr, S.R.O.                               | Czech Republic                           |
| Amlodipin/Atorvastatin Teva             | PT/H/1082/002                                    | 83/303/14-C                                                                                                                                                                                                                                                                                                                      | Teva Pharmaceuticals Cr, S.R.O.                               | Czech Republic                           |
| Amlodipina + Atorvastatina Actavis      | PT/H/0840/001 & PT/H/0840/002                    | 5575949 & 5575956 & 5576012                                                                                                                                                                                                                                                                                                      | Actavis Group Ptc Ehf.                                        | Portugal                                 |
| Amlodipina + Atorvastatina Krka         | SI/H/0142/002                                    | 5589064 & 5589072 & 5589106 & 5589114                                                                                                                                                                                                                                                                                            | Krka, D.D., Novo Mesto                                        | Portugal                                 |
| Amlodipina + Atorvastatina Krka         | SI/H/0142/003                                    | 5611017 & 5611025 & 5611033 & 5611041                                                                                                                                                                                                                                                                                            | Krka, D.D., Novo Mesto                                        | Portugal                                 |
| Amlodipina + Atorvastatina Ratiopharm   | PT/H/1082/001                                    | 5646567 & 5646575                                                                                                                                                                                                                                                                                                                | Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda | Portugal                                 |
| Amlodipina + Atorvastatina Ratiopharm   | PT/H/1082/002                                    | 5646633 & 5646641                                                                                                                                                                                                                                                                                                                | Ratiopharm-Comercio E Industria De Produtos Farmaceuticos Lda | Portugal                                 |
| Amlodipina + Atorvastatina Richter      | HU/H/0321/001 & HU/H/0321/004                    | 5582606 & 5582614 & 5582622 & 5582630 & 5582648 & 5582655 & 5582663 & 5582671 & 5582705 & 5582838 & 5582945                                                                                                                                                                                                                      | Gedeon Richter Plc.                                           | Portugal                                 |
| Amlodipina + Atorvastatina Richter      | HU/H/0321/003 & HU/H/0321/004                    | 5582713 & 5582721 & 5582739 & 5582747 & 5582754 & 5582762 & 5582770 & 5582804 & 5582812 & 5582820 & 5582846 & 5582853 & 5582861 & 5582879 & 5582903 & 5582911 & 5582929 & 5582937 & 5582952                                                                                                                                      | Gedeon Richter Plc.                                           | Portugal                                 |
| Amlodipina/Atorvastatina Krka           | SI/H/0143/002                                    | 5509/2013/01 & 5509/2013/02 & 5509/2013/03 & 5509/2013/04 & 5509/2013/05 & 5509/2013/06 & 5509/2013/07 & 5509/2013/08 & 5509/2013/09 & 5509/2013/10                                                                                                                                                                              | Krka, D.D., Novo Mesto                                        | Romania                                  |
| Amlodipina/Atorvastatina Krka           | SI/H/0143/003                                    | 6695/2014/01 & 6695/2014/02 &                                                                                                                                                                                                                                                                                                    | Krka, D.D., Novo Mesto                                        | Romania                                  |

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|                                         |                                               | 6695/2014/03 & 6695/2014/04 & 6695/2014/05 & 6695/2014/06 & 6695/2014/07 & 6695/2014/08 & 6695/2014/09 & 6695/2014/10                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                   |                                          |
| Amlodipine /Atorvastatin Krka           | SI/H/0143/002/DC                              | 13-0062                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Krka, D.D., Novo Mesto                            | Latvia                                   |
| Amlodipine Atorvastatin Actavis         | PT/H/0840/001 & PT/H/0840/002                 | MA628/10401 & MA628/10402                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Actavis Group Ptc Ehf.                            | Malta                                    |
| Amlodipine/ Atorvastatin Krka           | SI/H/0143/003                                 | 22093                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Krka, D.D., Novo Mesto                            | Poland                                   |
| Amlodipine/Atorvastatin Krka            | SI/H/0143/002                                 | 21201                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Krka, D.D., Novo Mesto                            | Poland                                   |
| Amlodipine/Atorvastatin Krka            | SI/H/0143/002                                 | LT/1/13/3223/001 & LT/1/13/3223/002 & LT/1/13/3223/003 & LT/1/13/3223/004 & LT/1/13/3223/005 & LT/1/13/3223/006 & LT/1/13/3223/007 & LT/1/13/3223/008 & LT/1/13/3223/009 & LT/1/13/3223/010                                                                                                                                                                                                                                                                                                                                                                                   | Krka, D.D., Novo Mesto                            | Lithuania                                |
| Amlodipine/Atorvastatin Krka            | SI/H/0143/003                                 | LT/1/13/3223/011 & LT/1/13/3223/012 & LT/1/13/3223/013 & LT/1/13/3223/014 & LT/1/13/3223/015 & LT/1/13/3223/016 & LT/1/13/3223/017 & LT/1/13/3223/018 & LT/1/13/3223/019 & LT/1/13/3223/020                                                                                                                                                                                                                                                                                                                                                                                   | Krka, D.D., Novo Mesto                            | Lithuania                                |
| Amlodipine/Atorvastatin Krka            | SI/H/0143/003/DC                              | 14-0132                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Krka, D.D., Novo Mesto                            | Latvia                                   |
| Amlodipine/Atorvastatin Polpharma       | CZ/H/0317/001 & CZ/H/0317/002                 | 83/264/14-C & 83/265/14-C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna | Czech Republic                           |
| Amlodipine/Atorvastatine Pfizer         | FR/H/0478/001 & FR/H/0478/002                 | 34009 219 316 7 9 & 34009 219 317 3 0 & 34009 219 319 6 9 & 34009 219 320 4 1 & 34009 219 321 0 2 & 34009 219 322 7 0 & 34009 219 323 3 1 & 34009 219 325 6 0 & 34009 219 326 2 1 & 34009 219 327 9 9 & 34009 219 328 5 0 & 34009 219 329 1 1 & 34009 219 331 6 1 & 34009 219 332 2 2 & 34009 581 436 8 7 & 34009 581 437 4 8 & 34009 581 438 0 9 & 34009 581 439 7 7 & 34009 581 440 5 9 & 34009 581 441 1 0 & 34009 581 442 8 8 & 34009 581 443 4 9 & 34009 581 444 0 0 & 34009 581 445 7 8 & 34009 581 446 3 9 & 34009 581 448 6 8 & 34009 581 449 2 9 & 34009 581 450 0 1 | Pfizer Holding France (S.C.A.)                    | France                                   |
| Amlodipino /Atorvastatina Richter       | HU/H/0321/001 & HU/H/0321/003 & HU/H/0321/004 | 701539-0 & 701548-2 & 701556-7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Gedeon Richter Plc.                               | Spain                                    |

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| Amlodipino/Atorvastatina Krka           | SI/H/0142/002                  | 78033                                                                                                                                                                                                                                                                                                                                                                 | Krka, D.D., Novo Mesto                            | Spain                                    |
| Amlodipino/Atorvastatina Krka           | SI/H/0142/003/DC               | 78853                                                                                                                                                                                                                                                                                                                                                                 | Krka, D.D., Novo Mesto                            | Spain                                    |
| Amlodipino/Atorvastatina Normon         |                                | 80473 & 80474                                                                                                                                                                                                                                                                                                                                                         | Laboratorios Normon, S.A.                         | Spain                                    |
| Amlodipină/Atorvastatină Teva           | PT/H/1082/001                  | 7298/2015/01-04                                                                                                                                                                                                                                                                                                                                                       | Teva Pharmaceuticals S.R.L                        | Romania                                  |
| Amlodipină/Atorvastatină Teva           | PT/H/1082/002                  | 7299/2015/01-04                                                                                                                                                                                                                                                                                                                                                       | Teva Pharmaceuticals S.R.L                        | Romania                                  |
| Amoriro                                 | PT/H/0841/001 & PT/H/0841/002  | 5575964 & 5575972 & 5576004                                                                                                                                                                                                                                                                                                                                           | Actavis Group Ptc Ehf.                            | Portugal                                 |
| Amoriro                                 | PT/H/0841/001 & PT/H/0841/002  | 58/0097/13-S & 58/0098/13-S                                                                                                                                                                                                                                                                                                                                           | Actavis Group Ptc Ehf.                            | Slovakia                                 |
| Amoriro                                 | PT/H/0841/001 & PT/H/0841/002  | MA628 10701 & MA628 10702                                                                                                                                                                                                                                                                                                                                             | Actavis Group Ptc Ehf.                            | Malta                                    |
| Aston                                   | CZ/H/0317/001 & CZ/H/0317/002  | 22173 & 22174                                                                                                                                                                                                                                                                                                                                                         | Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna | Poland                                   |
| Astucor                                 |                                | 67.593 & 67.594                                                                                                                                                                                                                                                                                                                                                       | Almirall, S.A.                                    | Spain                                    |
| Atorcombo                               |                                | OGYI-T-22522/01 & OGYI-T-22522/02 & OGYI-T-22522/03 & OGYI-T-22522/04 & OGYI-T-22522/05 & OGYI-T-22522/06 & OGYI-T-22522/07 & OGYI-T-22522/08 & OGYI-T-22522/09 & OGYI-T-22522/10 & OGYI-T-22522/11 & OGYI-T-22522/12 & OGYI-T-22522/13 & OGYI-T-22522/14 & OGYI-T-22522/15 & OGYI-T-22522/16 & OGYI-T-22522/17 & OGYI-T-22522/18 & OGYI-T-22522/19 & OGYI-T-22522/20 | Pharma-Regist Ltd                                 | Hungary                                  |
| Atordapin                               |                                | UP/I-530-09/12-01/405 & UP/I-530-09/12-01/406                                                                                                                                                                                                                                                                                                                         | Krka-Farma D.O.O.                                 | Croatia                                  |
| Atordapin                               | SI/H/0142/002                  | 21199                                                                                                                                                                                                                                                                                                                                                                 | Krka, D.D., Novo Mesto                            | Poland                                   |
| Atordapin                               | SI/H/0142/002                  | 5508/2013/01 & 5508/2013/02 & 5508/2013/03 & 5508/2013/04 & 5508/2013/05 & 5508/2013/06 & 5508/2013/07 & 5508/2013/08 & 5508/2013/09 & 5508/2013/10                                                                                                                                                                                                                   | Krka, D.D., Novo Mesto                            | Romania                                  |
| Atordapin                               | SI/H/0142/002                  | 83/240/13-C                                                                                                                                                                                                                                                                                                                                                           | Krka, D.D., Novo Mesto                            | Czech Republic                           |
| Atordapin                               | SI/H/0142/002                  | LT/1/13/3224/001 & LT/1/13/3224/002 & LT/1/13/3224/003 & LT/1/13/3224/004 & LT/1/13/3224/005 & LT/1/13/3224/006 & LT/1/13/3224/007 & LT/1/13/3224/008 &                                                                                                                                                                                                               | Krka, D.D., Novo Mesto                            | Lithuania                                |

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|                                         |                                               | LT/1/13/3224/009 & LT/1/13/3224/010                                                                                                                                                                                                                                                                                                                                     |                                    |                                          |
| Atordapin                               | SI/H/0142/002/DC                              | 58/0091/13-S                                                                                                                                                                                                                                                                                                                                                            | Krka, D.D., Novo Mesto             | Slovakia                                 |
| Atordapin                               | SI/H/0142/002/DC                              | OGYI-T-22437/01 & OGYI-T-22437/02 & OGYI-T-22437/03 & OGYI-T-22437/04 & OGYI-T-22437/05                                                                                                                                                                                                                                                                                 | Krka, D.D., Novo Mesto             | Hungary                                  |
| Atordapin                               | SI/H/0142/002/DC & SI/H/0142/003/DC           | 13-0059 & 14-0133                                                                                                                                                                                                                                                                                                                                                       | Krka, D.D., Novo Mesto             | Latvia                                   |
| Atordapin                               | SI/H/0142/003                                 | 22092                                                                                                                                                                                                                                                                                                                                                                   | Krka, D.D., Novo Mesto             | Poland                                   |
| Atordapin                               | SI/H/0142/003                                 | 58/0146/14-S                                                                                                                                                                                                                                                                                                                                                            | Krka, D.D., Novo Mesto             | Slovakia                                 |
| Atordapin                               | SI/H/0142/003                                 | 6694/2014/01 & 6694/2014/02 & 6694/2014/03 & 6694/2014/04 & 6694/2014/05 & 6694/2014/06 & 6694/2014/07 & 6694/2014/08 & 6694/2014/09 & 6694/2014/10                                                                                                                                                                                                                     | Krka, D.D., Novo Mesto             | Romania                                  |
| Atordapin                               | SI/H/0142/003                                 | 83/239/14-C                                                                                                                                                                                                                                                                                                                                                             | Krka, D.D., Novo Mesto             | Czech Republic                           |
| Atordapin                               | SI/H/0142/003                                 | LT/1/13/3224/011 & LT/1/13/3224/012 & LT/1/13/3224/013 & LT/1/13/3224/014 & LT/1/13/3224/015 & LT/1/13/3224/016 & LT/1/13/3224/017 & LT/1/13/3224/018 & LT/1/13/3224/019 & LT/1/13/3224/020                                                                                                                                                                             | Krka, D.D., Novo Mesto             | Lithuania                                |
| Atordapin                               | SI/H/0142/003                                 | OGYI-T-22437/06 & OGYI-T-22437/07 & OGYI-T-22437/08 & OGYI-T-22437/09 & OGYI-T-22437/10                                                                                                                                                                                                                                                                                 | Krka, D.D., Novo Mesto             | Hungary                                  |
| Atorvalan Comp.                         |                                               | 136033 & 136034                                                                                                                                                                                                                                                                                                                                                         | G.L. Pharma Gmbh                   | Austria                                  |
| Atorvastatiin+amlodipiin Krka           | SI/H/0143/003                                 | 845814                                                                                                                                                                                                                                                                                                                                                                  | Krka, D.D., Novo Mesto             | Estonia                                  |
| Atorvastatiin/Amlodipiin Krka           | SI/H/0143/002                                 | 811613                                                                                                                                                                                                                                                                                                                                                                  | Krka, D.D., Novo Mesto             | Estonia                                  |
| Atorvastatin/Amlodipin Richter          | HU/H/0321/001 & HU/H/0321/003 & HU/H/0321/004 | OGYI-T-22309/01 & OGYI-T-22309/02 & OGYI-T-22309/03 & OGYI-T-22309/04 & OGYI-T-22309/05 & OGYI-T-22309/06 & OGYI-T-22309/07 & OGYI-T-22309/08 & OGYI-T-22309/09 & OGYI-T-22309/10 & OGYI-T-22309/11 & OGYI-T-22309/12 & OGYI-T-22309/13 & OGYI-T-22309/14 & OGYI-T-22309/15 & OGYI-T-22309/16 & OGYI-T-22309/17 & OGYI-T-22309/18 & OGYI-T-22309/19 & OGYI-T-22309/20 & | Gedeon Richter Plc.                | Hungary                                  |

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|                                         |                                | OGYI-T-22309/21 & OGYI-T-22309/22 & OGYI-T-22309/23 & OGYI-T-22309/24 & OGYI-T-22309/25 & OGYI-T-22309/26 & OGYI-T-22309/27 & OGYI-T-22309/28 & OGYI-T-22309/29 & OGYI-T-22309/30                                                                                                                                                                                                                                                                                                                                                                                             |                                                |                                          |
| Atorvastatin/Amlodipine Teva            | PT/H/1082/001 & PT/H/1082/002  | LT/1/14/3620/003 & LT/1/14/3620/005                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Teva Pharma B.V.                               | Lithuania                                |
| Atorvox Plus                            | PT/H/1082/001                  | 22164                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Teva Pharmaceuticals Polska Sp. Z O.O.         | Poland                                   |
| Atorvox Plus                            | PT/H/1082/002                  | 22165                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Teva Pharmaceuticals Polska Sp. Z O.O.         | Poland                                   |
| Azilodis                                | 12/H/0086/001                  | 5585120 & 5585138 & 5585146 & 5585153 & 5585161 & 5585179 & 5585203 & 5585211 & 5585229 & 5585237 & 5585245 & 5585252                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Sigillata Limited                              | Portugal                                 |
| Azilodis                                | 12/H/0086/002                  | 5584966 & 5584974 & 5585005 & 5585013 & 5585021 & 5585039 & 5585047 & 5585054 & 5585062 & 5585070 & 5585104 & 5585112                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Sigillata Limited                              | Portugal                                 |
| Caduet                                  |                                | 6944/2006/01 & 6945/2006/01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Pfizer Europe Ma Eeig                          | Romania                                  |
| Caduet                                  |                                | UP/I-530-09/11-02/295 & UP/I-530-09/11-02/296                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Pfizer Croatia D.O.O.                          | Croatia                                  |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | 06-0020 & 06-0021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Pfizer Europe Ma Eeig                          | Latvia                                   |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | 1-26271 & 1-26273                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Pfizer Corporation Austria Gesellschaft M.B.H. | Austria                                  |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | 34009 369 293 2 6 & 34009 369 294 9 4 & 34009 369 295 5 5 & 34009 369 296 1 6 & 34009 369 297 8 4 & 34009 369 298 4 5 & 34009 369 299 0 6 & 34009 369 300 9 4 & 34009 369 301 5 5 & 34009 369 302 1 6 & 34009 369 303 8 4 & 34009 369 304 4 5 & 34009 369 305 0 6 & 34009 369 306 7 4 & 34009 375 754 8 5 & 34009 375 755 4 6 & 34009 566 837 5 8 & 34009 566 838 1 9 & 34009 566 839 8 7 & 34009 566 840 6 9 & 34009 566 841 2 0 & 34009 566 842 9 8 & 34009 566 843 5 9 & 34009 566 844 1 0 & 34009 566 845 8 8 & 34009 566 846 4 9 & 34009 566 847 0 0 & 34009 566 848 7 8 | Pfizer Holding France (S.C.A.)                 | France                                   |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | 5674387 & 5674486 & 5674585 & 5674684                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Laboratórios Pfizer, Lda.                      | Portugal                                 |

| Product Name (in authorisation country) | MRP / DCP Authorisation number | National Authorisation Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | MAH of product in the member state | Member State where product is authorised |
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|                                         |                                | & 5674783 & 5674882 & 5674981 & 5675087 & 5675186 & 5675285                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                    |                                          |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | 67.325 & 67.326                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Pfizer, S.L.                       | Spain                                    |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | 83/616/05-C & 83/617/05-C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Pfizer, Spol. S R.O.               | Czech Republic                           |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | H/06/00321/001 & H/06/00321/002 & H/06/00321/003 & H/06/00321/004 & H/06/00321/005 & H/06/00321/006 & H/06/00321/007 & H/06/00321/008 & H/06/00321/009 & H/06/00321/010 & H/06/00321/011 & H/06/00321/012 & H/06/00321/013 & H/06/00321/014 & H/06/00321/015 & H/06/00321/016 & H/06/00321/017 & H/06/00321/018 & H/06/00321/019 & H/06/00321/020 & H/06/00321/021 & H/06/00321/022 & H/06/00321/023 & H/06/00321/024 & H/06/00321/025 & H/06/00321/026 & H/06/00321/027 & H/06/00321/028                   | Pfizer Luxembourg Sarl             | Slovenia                                 |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | LT/1/06/0513/001 & LT/1/06/0513/002 & LT/1/06/0513/003 & LT/1/06/0513/004 & LT/1/06/0513/005 & LT/1/06/0513/006 & LT/1/06/0513/007 & LT/1/06/0513/008 & LT/1/06/0513/009 & LT/1/06/0513/010 & LT/1/06/0513/011 & LT/1/06/0513/012 & LT/1/06/0513/013 & LT/1/06/0513/014 & LT/1/06/0513/015 & LT/1/06/0513/016 & LT/1/06/0513/017 & LT/1/06/0513/018 & LT/1/06/0513/019 & LT/1/06/0513/020 & LT/1/06/0513/021 & LT/1/06/0513/022 & LT/1/06/0513/023 & LT/1/06/0513/024 & LT/1/06/0513/025 & LT/1/06/0513/026 | Pfizer Europe Ma Eeig              | Lithuania                                |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | MA505/04801 & MA505/04802                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Pfizer Hellas, A.E.                | Malta                                    |
| Caduet                                  | FR/H/0280/001 & FR/H/0280/002  | OGYI-T-10 613/01 & OGYI-T-10 613/02                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Pfizer Kft.                        | Hungary                                  |
| Crystaliro                              | PT/H/0840/001 & PT/H/0840/002  | 30522 & 30523                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Actavis Group Ptc Ehf.             | Finland                                  |
| Dicartil                                | FR/H/0478/001 & FR/H/0478/002  | 58/0332/11-S & 58/0333/11-S                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Pfizer Europe Ma Eeig              | Slovakia                                 |
| Dicartil                                | FR/H/0478/001 & FR/H/0478/002  | OGYI-T-21776/01 & OGYI-T-21776/02 & OGYI-T-21776/03 & OGYI-T-21776/04 &                                                                                                                                                                                                                                                                                                                                                                                                                                     | Pfizer Kft.                        | Hungary                                  |

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|                                         |                                                               | OGYI-T-21776/05 & OGYI-T-21776/06 & OGYI-T-21776/07 & OGYI-T-21776/08 & OGYI-T-21776/09 & OGYI-T-21776/10 & OGYI-T-21776/11 & OGYI-T-21776/12 & OGYI-T-21776/13 & OGYI-T-21776/14 & OGYI-T-21776/15 & OGYI-T-21776/16 & OGYI-T-21776/17 & OGYI-T-21776/18 & OGYI-T-21776/19 & OGYI-T-21776/20 & OGYI-T-21776/21 & OGYI-T-21776/22 & OGYI-T-21776/23 & OGYI-T-21776/24 & OGYI-T-21776/25 & OGYI-T-21776/26 & OGYI-T-21776/27 |                                    |                                          |
| Duplecor                                | HU/H/0248/001 & HU/H/0248/002 & HU/H/0248/003 & HU/H/0248/004 | 11- 0286 & 11- 0287 & 11- 0289 & 11-0288                                                                                                                                                                                                                                                                                                                                                                                    | Gedeon Richter Plc.                | Latvia                                   |
| Duplecor                                | HU/H/0248/001 & HU/H/0248/002 & HU/H/0248/003 & HU/H/0248/004 | 3402/2011/01 & 3403/2011/01 & 3404/2011/01 & 3405/2011/01                                                                                                                                                                                                                                                                                                                                                                   | Gedeon Richter România S.A.        | Romania                                  |
| Duplecor                                | HU/H/0248/001 & HU/H/0248/002 & HU/H/0248/003 & HU/H/0248/004 | 740211 & 740311 & 740411 & 740511                                                                                                                                                                                                                                                                                                                                                                                           | Gedeon Richter Plc.                | Estonia                                  |
| Fernastin                               | 12/H/0084/001 & 12/H/0084/002                                 | 5585260 & 5585278 & 5585302 & 5585310 & 5585328 & 5585336 & 5585344 & 5585351 & 5585369 & 5585377 & 5585401 & 5585427 & 5585435 & 5585443 & 5585450 & 5585468 & 5585476 & 5585500 & 5585518 & 5585526 & 5585534 & 5585542 & 5585559                                                                                                                                                                                         | Sigillata Limited                  | Portugal                                 |
| Fernastin                               | 12/H/0084/002                                                 | 5585419                                                                                                                                                                                                                                                                                                                                                                                                                     | Sigillata Limited                  | Portugal                                 |
| Lidorat                                 | HU/H/0320/001 & HU/H/0320/003 & HU/H/0320/004                 | 1-31754 & 1-31755 & 1-31756                                                                                                                                                                                                                                                                                                                                                                                                 | Gedeon Richter Plc.                | Austria                                  |
| Lidorat                                 | HU/H/0320/001 & HU/H/0320/003 & HU/H/0320/004                 | 702658-7 & 78827 & 78828                                                                                                                                                                                                                                                                                                                                                                                                    | Medimpex France S.A.               | Spain                                    |
| Lidorat                                 | HU/H/0320/001 & HU/H/0320/003 & HU/H/0320/004                 | BE427646 & BE427655 & BE427664                                                                                                                                                                                                                                                                                                                                                                                              | Medimpex France S.A.               | Belgium                                  |
| Lidorat                                 | HU/H/0320/001 & HU/H/0320/003 & HU/H/0320/004                 | OGYI-T-22308/01 & OGYI-T-22308/02 & OGYI-T-22308/03 & OGYI-T-22308/04 & OGYI-T-22308/05 & OGYI-T-22308/06 & OGYI-T-22308/07 & OGYI-T-22308/08 & OGYI-T-22308/09 & OGYI-T-22308/10 & OGYI-T-22308/11 & OGYI-T-22308/12 & OGYI-T-22308/13 & OGYI-T-22308/14 &                                                                                                                                                                 | Gedeon Richter Plc.                | Hungary                                  |

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|                                         |                                               | OGYI-T-22308/15 & OGYI-T-22308/16 & OGYI-T-22308/17 & OGYI-T-22308/18 & OGYI-T-22308/19 & OGYI-T-22308/20 & OGYI-T-22308/21 & OGYI-T-22308/22 & OGYI-T-22308/23 & OGYI-T-22308/24 & OGYI-T-22308/25 & OGYI-T-22308/26 & OGYI-T-22308/27 & OGYI-T-22308/28 & OGYI-T-22308/29 & OGYI-T-22308/30 |                                                   |                                          |
| Somozig                                 | 12/H/0087/001 & 12/H/0087/002                 | 5584669 & 5584677 & 5584701 & 5584719 & 5584727 & 5584735 & 5584743 & 5584750 & 5584768 & 5584776 & 5584800 & 5584818 & 5584826 & 5584834 & 5584842 & 5584859 & 5584867 & 5584875 & 5584909 & 5584917 & 5584925 & 5584941 & 5584958                                                           | Sigillata Limited                                 | Portugal                                 |
| Stobetin                                | CZ/H/0317/001 & CZ/H/0317/002                 | 58/0159/14-S & 58/0160/14-S                                                                                                                                                                                                                                                                   | Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna | Slovakia                                 |
| Torvalipin Plus                         | PT/H/0841/001 & PT/H/0841/002                 | 5616/2013/01-12 & 5617/2013/01-12                                                                                                                                                                                                                                                             | Actavis Group Ptc Ehf.                            | Romania                                  |
| Torviman                                | HU/H/0322/001 & HU/H/0322/003 & HU/H/0322/004 | OGYI-T-22310/01 & OGYI-T-22310/02 & OGYI-T-22310/03 & OGYI-T-22310/04 & OGYI-T-22310/05 & OGYI-T-22310/06 & OGYI-T-22310/07 & OGYI-T-22310/08 & OGYI-T-22310/09                                                                                                                               | Gedeon Richter Plc.                               | Hungary                                  |
| Vidozol                                 | 12/H/0085/001 & 12/H/0085/002                 | 5584362 & 5584370 & 5584404 & 5584412 & 5584420 & 5584438 & 5584446 & 5584453 & 5584461 & 5584479 & 5584503 & 5584511 & 5584529 & 5584537 & 5584545 & 5584552 & 5584560 & 5584578 & 5584602 & 5584610 & 5584628 & 5584636 & 5584644 & 5584651                                                 | Sigillata Limited                                 | Portugal                                 |
| Zarvalor                                | CZ/H/317/001-002/DC                           | 4267/21-1-2015 & 4268/21-1-2015                                                                                                                                                                                                                                                               | Win Medica Ltd                                    | Greece                                   |
| аванор плюс                             | PT/H/1082/001                                 | 20140356                                                                                                                                                                                                                                                                                      | Teva Pharmaceuticals Bulgaria Eood                | Bulgaria                                 |
| аванор плюс                             | PT/H/1082/002                                 | 20140357                                                                                                                                                                                                                                                                                      | Teva Pharmaceutical Bulgaria Eood                 | Bulgaria                                 |
| амлатор                                 | HU/H/0248/001 & HU/H/0248/002 & HU/H/0248/004 | 20110295 & 20110296 & 20110298                                                                                                                                                                                                                                                                | Gedeon Richter Plc.                               | Bulgaria                                 |
| амлатор                                 | HU/H/0248/003                                 | 20110297                                                                                                                                                                                                                                                                                      | Gedeon Richter Plc.                               | Bulgaria                                 |
| амлодипин/Аторвастатин Krka             | SI/H/0143/002                                 | 20130259                                                                                                                                                                                                                                                                                      | Krka, D.D., Novo Mesto                            | Bulgaria                                 |

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| амлодипин/Аторвастатин<br>крка          | SI/H/0143/003/DC               | 20140231                      | Krka, D.D., Novo Mesto             | Bulgaria                                 |
| атордапин                               | SI/H/0142/002                  | 20130258                      | Krka, D.D., Novo Mesto             | Bulgaria                                 |
| атордапин                               | SI/H/0142/003/DC               | 20140230                      | Krka, D.D., Novo Mesto             | Bulgaria                                 |
| кадует                                  |                                | 20060484 & 20060485           | Pfizer Europe Ma Eeig              | Bulgaria                                 |
| лукстанор                               | PT/H/0841/001 & PT/H/0841/002  | 20130199 & 20130200           | Actavis Group Ptc Ehf.             | Bulgaria                                 |