



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 May 2016  
EMA/388981/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: lisinopril

Procedure no.: PSUSA/00001894/201509



| 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 |
|--------------------------------------------|-------------------------------------------------|------------------------------------------------------------------|---------------------------------------------|------------------------------------------|
| Alapril                                    |                                                 | 026837017 \$ 026837029 \$ 026837043 \$ 026837056                 | Mediolanum Farmaceutici Spa                 | Italy                                    |
| Lisinopril Aurobindo                       | NL/H/1976/002                                   | 040262228/M                                                      | Aurobindo Pharma (Italia) S.R.L.            | Italy                                    |
| Lisinopril Aurobindo                       | NL/H/1976/003                                   | 81206.00.00                                                      | Aurobindo Pharma Gmbh                       | Germany                                  |
| Lisinopril Aurobindo                       | NL/H/1976/003 \$ NL/H/1976/004                  | 5375829 \$ 5375837                                               | Aurobindo Pharma (Portugal), Unipessoal Lda | Portugal                                 |
| Lisinopril Aurobindo                       | NL/H/1976/004                                   | 81207.00.00                                                      | Aurobindo Pharma Gmbh                       | Germany                                  |
| Lisinopril Aurobindo                       | NL/H/1976/004                                   | RVG 32686                                                        | Aurobindo Pharma B.V.                       | Netherlands                              |
| Lisinopril Bristol Laboratories            |                                                 | PL 17907/0236                                                    | Bristol Laboratories Ltd (Berkhamsted)      | United Kingdom                           |
| Lisinopril Bristol Laboratories            |                                                 | PL 17907/0237 \$ PL 17907/0239                                   | Bristol Laboratories Ltd (Berkhamsted)      | United Kingdom                           |
| Lisinopril Bristol Laboratories            |                                                 | PL 17907/0238                                                    | Bristol Laboratories Ltd (Berkhamsted)      | United Kingdom                           |
| Lisinopril Brown & Burk Uk                 |                                                 | PL 25298/0118 \$ PL 25298/0119 \$ PL 25298/0120 \$ PL 25298/0121 | Brown & Burk Uk Limited                     | United Kingdom                           |
| Lisinopril Crescent Pharma                 |                                                 | PL 20416/0351 \$ PL 20416/0352 \$ PL 20416/0353 \$ PL 20416/0354 | Crescent Pharma Limited                     | United Kingdom                           |
| Lisinopril Dihydrate Astrazeneca           |                                                 | PL 17901/0060                                                    | Astrazeneca Uk Limited                      | United Kingdom                           |
| Lisinopril Dihydrate Astrazeneca           | SE/H/0527/001                                   | 1-21290                                                          | Astrazeneca Osterreich Gmbh                 | Austria                                  |
| Zestril (Lisinopril Dihydrate Astrazeneca) | SE/H/0527/001                                   | 11646                                                            | Astrazeneca Ab                              | Sweden                                   |
| Lisinopril Dihydrate Astrazeneca           | SE/H/0527/001                                   | PA 970/23/1                                                      | Astrazeneca Uk Limited                      | Ireland                                  |
| Lisinopril Dihydrate Astrazeneca           | SE/H/0527/002                                   | 26834010 \$ 26834059 \$ 26834061                                 | Astrazeneca S.P.A.                          | Italy                                    |
| Lisinopril Dihydrate Astrazeneca           | SE/H/0527/002 \$ SE/H/0527/003 \$ SE/H/0527/004 | 12874 \$ 12875 \$ 12876                                          | Astrazeneca Uk Limited                      | Cyprus                                   |
| Lisinopril Dihydrate Astrazeneca           | SE/H/0527/002 \$ SE/H/0527/003 \$ SE/H/0527/004 | 3788/05                                                          | Astrazeneca S.A                             | Greece                                   |

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|-----------------------------------------------|-------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------|
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/003 \$<br>SE/H/0527/004 | 4545380 \$ 8708206 \$ 8708214 \$<br>8708222 \$ 8708230 \$ 8708248 \$<br>8708255                                         | Astrazeneca Produtos<br>Farmaceuticos Lda. | Portugal       |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/003 \$<br>SE/H/0527/004 | BE141556 \$ BE141671 \$ BE237413<br>\$ BE396611 \$ BE396627 \$<br>BE396645 \$ BE396654 \$ BE396672<br>\$ BE396681       | Nv Astrazeneca Sa                          | Belgium        |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/003 \$<br>SE/H/0527/004 | PL 17901/0061 \$ PL 17901/0062 \$<br>PL 17901/0063                                                                      | Astrazeneca Uk Limited                     | United Kingdom |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/003 \$<br>SE/H/0527/004 | RVG 12560 \$ RVG 12561 \$ RVG<br>12562                                                                                  | Astrazeneca Bv                             | Netherlands    |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/004                     | 0173/11091286 \$ 0173/11091287                                                                                          | Nv Astrazeneca Sa                          | Luxembourg     |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/004                     | 1-19013 \$ 1-19014 \$ 1-19015                                                                                           | Astrazeneca Osterreich Gmbh                | Austria        |
| Zestril (Lisinopril<br>Dihydrate Astrazeneca) | SE/H/0527/002 \$<br>SE/H/0527/004                     | 10870 \$ 10872                                                                                                          | Astrazeneca Ab                             | Sweden         |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/004                     | 34009 329 99040 \$ 34009 329<br>99101 \$ 34009 398 90234 \$ 34009<br>398 90463 \$ 34009 559 18103 \$<br>34009 559 18271 | Astrazeneca S.A.S.                         | France         |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/002 \$<br>SE/H/0527/004                     | PA 970/23/2 \$ PA 970/23/3 \$ PA<br>970/23/4                                                                            | Astrazeneca Uk Limited                     | Ireland        |
| Zestril (Lisinopril<br>Dihydrate Astrazeneca) | SE/H/0527/003                                         | 10871                                                                                                                   | Astrazeneca Ab                             | Sweden         |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/003                                         | 26834034                                                                                                                | Astrazeneca S.P.A.                         | Italy          |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/004                                         | 044/01203                                                                                                               | Astrazeneca Uk Limited                     | Malta          |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/004                                         | 26834022 \$ 26834073 \$ 26834085                                                                                        | Astrazeneca S.P.A.                         | Italy          |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/004                                         | 59.127                                                                                                                  | Astrazeneca Farmaceutica Spain<br>S.A.     | Spain          |
| Lisinopril Dihydrate<br>Astrazeneca           | SE/H/0527/005                                         | 1-23335                                                                                                                 | Astrazeneca Osterreich Gmbh                | Austria        |
| Zestril (Lisinopril<br>Dihydrate Astrazeneca) | SE/H/0527/005                                         | 15268                                                                                                                   | Astrazeneca Ab                             | Sweden         |

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| Lisinopril Dihydrate<br>Astrazeneca | SE/H/0527/005                                                             | RVG 24015                                                                                                                                                                          | Astrazeneca Bv              | Netherlands    |
| Lisinopril Pch                      |                                                                           | RVG 33797                                                                                                                                                                          | Pharmachemie B.V            | Netherlands    |
| Lisinopril Sandoz                   | UK/H/0551/004                                                             | BE244982                                                                                                                                                                           | Sandoz N.V.                 | Belgium        |
| Lisinopril Sandoz Ltd               | UK/H/0551/001 \$<br>UK/H/0551/002 \$<br>UK/H/0551/003 \$<br>UK/H/0551/004 | PL 04416/1034 \$ PL 04416/1035 \$<br>PL 04416/1036 \$ PL 04416/1037                                                                                                                | Sandoz Ltd                  | United Kingdom |
| Lisinopril Tillomed<br>Laboratories |                                                                           | PL 11311/0394                                                                                                                                                                      | Tillomed Laboratories Ltd   | United Kingdom |
| Lisinopril Tillomed<br>Laboratories |                                                                           | PL 11311/0395                                                                                                                                                                      | Tillomed Laboratories Ltd   | United Kingdom |
| Lisinopril Tillomed<br>Laboratories |                                                                           | PL 11311/0396 \$ PL 11311/0397                                                                                                                                                     | Tillomed Laboratories Ltd   | United Kingdom |
| Lisipril                            | 10690/02 \$ 10691/02 \$<br>10692/02                                       | 58/382/03-C \$ 58/383/03-C \$<br>58/384/03-C                                                                                                                                       | Hexal Ag                    | Czech Republic |
| Lisipril                            | 10690/02 \$ 10691/02 \$<br>10692/02                                       | 58/382/03-C \$ 58/383/03-C \$<br>58/384/03-C                                                                                                                                       | Hexal Ag                    | Czech Republic |
| Prinivil                            |                                                                           | 026830012 \$ 026830024                                                                                                                                                             | Mediolanum Farmaceutici Spa | Italy          |
| Prinivil                            |                                                                           | 31449 329 987-3 9 \$ 34009 329<br>989-6 8 \$ 34009 371 562-7 1 \$<br>34009 371 563-3 2 \$ 34009 371<br>763-2 3 \$ 34009 556 479-9 7 \$<br>34009 556 480-7 9 \$ 34009371<br>764-9 1 | Msd France                  | France         |
| Prinivil                            |                                                                           | 4599387 \$ 4599486 \$ 5469986 \$<br>870 83 21 \$ 8708305 \$ 8708313 \$<br>8708347                                                                                                  | Merck Sharp & Dohme, Lda.   | Portugal       |
| Prinivil                            |                                                                           | 4864 \$ 4865 \$ 4866                                                                                                                                                               | Msd Polska Sp. Z O.O.       | Poland         |
| Prinivil                            |                                                                           | 59.128 \$ 59.129                                                                                                                                                                   | Frosst Ibérica, S.A.        | Spain          |
| Prinivil                            |                                                                           | UP/I-530-09/09-02/240                                                                                                                                                              | Merck Sharp & Dohme D.O.O.  | Croatia        |
| Prinivil                            |                                                                           | UP/I-530-09/09-02/241 \$ UP/I-530-<br>09/09-02/242                                                                                                                                 | Merck Sharp & Dohme D.O.O.  | Croatia        |

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|----------------------|---------------|---------------------------------|------------------------|--------|
| Prinivil δισκία 10mg |               | 29374                           | Vianex Sa              | Greece |
| Prinivil δισκία 20mg |               | 29108                           | Vianex Sa              | Greece |
| Prinivil δισκία 40mg |               | 29373                           | Vianex Sa              | Greece |
| Prinivil δισκία 5mg  |               | 29375                           | Vianex Sa              | Greece |
| Zestril              |               | MA 044/01201                    | Astrazeneca Uk Limited | Malta  |
| Zestril              |               | MA 044/01202                    | Astrazeneca Uk Limited | Malta  |
| ZESTRIL TAB 10MG/TAB | SE/H/527/03   | 31330/3-5-2012, 12186/16-2-2015 | Astrazeneca S.A        | Greece |
| ZESTRIL TAB 20MG/TAB | SE/H/527/04   | 31331/3-5-2012, 12186/16-2-2015 | Astrazeneca S.A        | Greece |
| ZESTRIL TAB 5MG/TAB  | SE/H/527/02   | 31329/3-5-2012, 12186/16-2-2015 | Astrazeneca S.A        | Greece |
| Zestril              | SE/H/0527/001 | 7812                            | Astrazeneca AS         | Norway |
| Zestril              | SE/H/0527/002 | 7635                            | Astrazeneca AS         | Norway |
| Zestril              | SE/H/0527/003 | 7636                            | Astrazeneca AS         | Norway |
| Zestril              | SE/H/0527/004 | 7637                            | Astrazeneca AS         | Norway |