



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 December 2015  
EMA/85654/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: amlodipine besilate / ramipril

Procedure no.: PSUSA/00000181/201503



| 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 |
|-----------------------------------------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------|------------------------------------|------------------------------------------|
| Amirap                                  | AT/H/0402/001-005            | 58/0181/12-S \$ 58/0182/12-S \$ 58/0183/12-S \$ 58/0184/12-S \$ 58/0185/12-S                                                   | Sandoz Pharmaceuticals D.D.        | Slovakia                                 |
| Amlopin Duo                             | AT/H/0402/002                | 20120330                                                                                                                       | Sandoz Pharmaceuticals D.D.        | Bulgaria                                 |
| Amrap                                   | SE/H/1339/001-005/DC         | 22122 \$ 22123 \$ 22124 \$ 22125 \$ 22126                                                                                      | Zentiva, K.S.                      | Poland                                   |
| Ramlon                                  | HU/H/0303/001-005/DC         | 12-0063 \$ 12-0064 \$ 12-0065 \$ 12-0066 \$ 12-0067                                                                            | Egis Pharmaceuticals Plc           | Latvia                                   |
| Egiramlon                               | HU/H/0303/001-005/DC         | 19611 \$ 19612 \$ 19613 \$ 19614                                                                                               | Proterapia                         | Poland                                   |
| Egiramlon                               | HU/H/0303/001-005/DC         | 20120045 \$ 20120046 \$ 20120047 \$ 20120048 \$ 20120049                                                                       | Egis Pharmaceuticals Plc           | Bulgaria                                 |
| Egiramlon                               | HU/H/0303/001-005/DC         | 4495/2012/01-05 \$ 4496/2012/01-05 \$ 4497/2012/01-05 \$ 4498/2012/01-05 \$ 4499/2012/01-05                                    | Egis Pharmaceuticals Plc           | Romania                                  |
| Egiramlon                               | HU/H/0303/001-005/DC         | 58/0743/11-S \$ 58/0744/11-S \$ 58/0745/11-S \$ 58/0746/11-S \$ 58/0747/11-S                                                   | Egis Pharmaceuticals Plc           | Slovakia                                 |
| Egiramlon                               | HU/H/0303/001-005/DC         | 58/837/11-C \$ 58/838/11-C \$ 58/839/11-C \$ 58/840/11-C \$ 58/841/11-C                                                        | Egis Pharmaceuticals Plc           | Czech Republic                           |
| Egiramlon                               | HU/H/0303/001-005/DC         | OGYI-T-22016/01-19                                                                                                             | Egis Pharmaceuticals Plc           | Hungary                                  |
| Icomb                                   | AT/H/0469/001-005            | 042384014 \$ 042384026 \$ 042384038 \$ 042384040 \$ 042384053 \$ 042384065 \$ 042384077 \$ 042384089 \$ 042384091 \$ 042384103 | Pfizer Italia S.R.L.               | Italy                                    |
| Parvati                                 |                              | 043322015 \$ 043322027 \$ 043322039 \$ 043322041 \$ 043322054                                                                  | Brunifarma Research Srl            | Italy                                    |
| Piramil Combi                           | AT/H/0402/005                | 58/364/12-C                                                                                                                    | Sandoz S.R.O.                      | Czech Republic                           |

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|-----------------------------------------|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------------------------|
| Piramil Combi                           | AT/H/0402/002 \$<br>AT/H/0402/003 \$<br>AT/H/0402/004                     | 58/361/12-C \$ 58/362/12-C \$<br>58/363/12-C                                                      | Sandoz S.R.O.                                  | Czech Republic                           |
| Presucomb                               | SE/H/1340/001-005                                                         | 14-0189 \$ 14-0190 \$ 14-0191 \$<br>14-0192 \$ 14-0193                                            | Pharmaswiss česká Republika S.R.O.             | Latvia                                   |
| Presucomb                               | SE/H/1340/001-005                                                         | 58/0063/14-S \$ 58/0277/14-S \$<br>58/0278/14-S \$ 58/0279/14-S \$<br>58/0280/14-S                | Pharmaswiss česká Republika S.R.O.             | Slovakia                                 |
| Presucomb                               | SE/H/1340/001-005                                                         | 851114 \$ 851214 \$ 851314 \$<br>851414 \$ 851814                                                 | Pharmaswiss česká Republika S.R.O.             | Estonia                                  |
| Presucomb                               | SE/H/1340/001-005 \$<br>SE/H/1340/05/DC                                   | LT/1/14/3615/001-050                                                                              | Pharmaswiss česká Republika S.R.O.             | Lithuania                                |
| Presucomb                               | SE/H/1340/001-005/DC                                                      | 4628/22.01.15 \$ 4775/22.01.15 \$<br>4776/22.01.15 \$ 4777/22.01.15 \$<br>4778/22.01.15           | Pharmaswiss česká Republika S.R.O.             | Greece                                   |
| Prylar                                  | SE/H/1397/001-005/DC                                                      | 4628/22-1-2015 \$ 4629/22-1-<br>2015 \$ 4630/22-1-2015 \$<br>4631/22-1-2015 \$ 4632/22-1-<br>2015 | Adamed                                         | Greece                                   |
| Ramantal                                |                                                                           | 043313016 \$ 043313028 \$<br>043313030 \$ 043313042 \$<br>043313055                               | Errekappa Euroterapici Spa                     | Italy                                    |
| Ramdacordia                             | AT/H/0402/001-005                                                         | 785612 \$ 785712 \$ 785812 \$<br>785912 \$ 786012                                                 | Sandoz Pharmaceuticals D.D.                    | Estonia                                  |
| Ramdacordia                             | AT/H/0402/002 \$<br>AT/H/0402/003 \$<br>AT/H/0402/004 \$<br>AT/H/0402/005 | 12-0136 \$ 12-0137 \$ 12-0138 \$<br>12-0139                                                       | Sandoz Pharmaceuticals D.D.                    | Latvia                                   |
| Ramipril Plus Amlodipin Hexal           | AT/H/0402/001 \$<br>AT/H/0402/003                                         | 84284.00.00 \$ 84286.00.00                                                                        | Hexal Ag                                       | Germany                                  |
| Ramipril Plus Amlodipin Hexal           | AT/H/0402/002 \$<br>AT/H/0402/004 \$<br>AT/H/0402/005                     | 84285.00.00 \$ 84287.00.00 \$<br>84288.00.00                                                      | Hexal Ag                                       | Germany                                  |
| Ramipril/Amlodipin                      | AT/H/0469/004                                                             | 135108                                                                                            | Pfizer Corporation Austria Gesellschaft M.B.H. | Austria                                  |

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| Ramipril/Amlodipin Genericon            | SE/H/1336/001-005                                                                     | 135662 \$ 135663 \$ 135664 \$ 135665 \$ 135666                                                          | Genericon Pharma Gesellschaft M.B.H.           | Austria                                  |
| Ramipril/Amlodipin Pfizer               | AT/H/0469/001 \$<br>AT/H/0469/002 \$<br>AT/H/0469/003 \$<br>AT/H/0469/005             | 135105 \$ 135106 \$ 135107 \$ 135109                                                                    | Pfizer Corporation Austria Gesellschaft M.B.H. | Austria                                  |
| Ramipril/Amlodipin Sandoz               | AT/H/0402/001-005                                                                     | 1-31215 \$ 1-31216 \$ 1-31217 \$ 1-31218 \$ 1-31219                                                     | Sandoz Gmbh                                    | Austria                                  |
| Ramipril/Amlodipin Zentiva              | SE/H/1339/001-005/DC                                                                  | 20140227 \$ 20140228 \$ 20140229 \$ 20140232 \$ 20140233                                                | Zentiva, K.S.                                  | Bulgaria                                 |
| Ramipril/Amlodipin Zentiva              | SE/H/1339/001-005/DC                                                                  | 49212 \$ 49213 \$ 49214 \$ 49215 \$ 49216                                                               | Zentiva, K.S.                                  | Sweden                                   |
| Ramipril/Amlodipin Zentiva              | SE/H/1339/001-005/DC                                                                  | 58/0284/14-S \$ 58/0285/14-S \$ 58/0286/14-S \$ 58/0287/14-S \$ 58/0288/14-S                            | Zentiva, K.S.                                  | Slovakia                                 |
| Tritace Combi                           | SE/H/1339/001-005/DC                                                                  | 58/333/14-C \$ 58/334/14-C \$ 58/335/14-C \$ 58/336/14-C \$ 58/337/14-C                                 | Zentiva, K.S.                                  | Czech Republic                           |
| Ramipril/Amlodipina Adamed              | SE/H/1336/001-005/DC                                                                  | 7199/2014/01-10 \$<br>7200/2014/01-10 \$<br>7201/2014/01-10 \$<br>7202/2014/01-10 \$<br>7203/2014/01-10 | Adamed                                         | Romania                                  |
| Ramipril/Amlodipine                     | SE/H/1340/001-002                                                                     | H/14/1931/001-050                                                                                       | Pharmaswiss česká republika S.R.O.             | Slovenia                                 |
| Ramipril/Amlodipine Adamed              | SE/H/1336/001-005                                                                     | 49203, 49204, 49205, 49206, 49207                                                                       | Adamed                                         | Sweden                                   |
| Ramipril/Amlodipine Glenmark            | SE/H/1337/001/DC \$<br>SE/H/1337/002/DC \$<br>SE/H/1337/003/DC \$<br>SE/H/1337/004/DC | 49208 \$ 49209 \$ 49210 \$ 49211                                                                        | Glenmark Pharmaceuticals S.R.O.                | Sweden                                   |
| Ramipril/Amlodipine Pharmaswiss         | SE/H/1340/001-005                                                                     | 49217 \$ 49218 \$ 49219 \$ 49220 \$ 49221                                                               | Pharmaswiss česká republika S.R.O.             | Sweden                                   |

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| Ramizek                                 | SE/H/1336/001-005                                                                     | 58/377/14-C \$ 58/378/14-C \$ 58/379/14-C \$ 58/380/14-C \$ 58/381/14-C           | Adamed Sp. Z o.o.                  | Czech Republic                           |
| Ramizek Combi                           | SE/H/1336/001 \$<br>SE/H/1336/002 \$<br>SE/H/1336/004 \$<br>SE/H/1336/005             | 21904 \$ 21905 \$ 21907 \$ 21908                                                  | Adamed                             | Poland                                   |
| Ramizek Combi                           | SE/H/1336/003                                                                         | 21906                                                                             | Adamed                             | Poland                                   |
| Ramlon                                  | HU/H/0303/001-005/DC                                                                  | LT/1/12/2892/001-025                                                              | Egis Pharmaceuticals Plc           | Lithuania                                |
| Ramlora                                 | SE/H/1337/001 \$<br>SE/H/1337/002 \$<br>SE/H/1337/003 \$<br>SE/H/1337/004             | 6608/2014/01-10 \$<br>6609/2014/01-10 \$<br>6610/2014/01-10 \$<br>6611/2014/01-10 | Glenmark Pharmaceuticals S.R.O.    | Romania                                  |
| Ramomark                                | SE/H/1337/001 \$<br>SE/H/1337/002 \$<br>SE/H/1337/003 \$<br>SE/H/1337/004             | 58/0204/14-S \$ 58/0205/14-S \$ 58/0206/14-S \$ 58/0207/14-S                      | Glenmark Pharmaceuticals S.R.O.    | Slovakia                                 |
| Ramomark                                | SE/H/1337/001/DC \$<br>SE/H/1337/002/DC \$<br>SE/H/1337/003/DC \$<br>SE/H/1337/004/DC | 58/281/14-C \$ 58/282/14-C \$ 58/283/14-C \$ 58/284/14-C                          | Glenmark Pharmaceuticals S.R.O.    | Czech Republic                           |
| Sumilar                                 | AT/H/0402/002 \$<br>AT/H/0402/003 \$<br>AT/H/0402/004 \$<br>AT/H/0402/005             | 20264 \$ 20265 \$ 20266 \$ 20267                                                  | Sandoz Gmbh                        | Poland                                   |
| Tonotec                                 | DE/H/3919/001-005/DC \$<br>DE/H/3919/002 \$<br>DE/H/3919/003 \$<br>DE/H/3919/004      | 88598.00.00, \$88599.00.00 \$<br>88600.00.00 \$ 88601.00.00 \$<br>88602.00.00     | Ucb Pharma Gmbh (Monheim De)       | Germany                                  |
| Triamlo                                 | SE/H/1339/001-005/DC                                                                  | 022103 \$ 022104 \$ 022105 \$ 022106 \$ 022107                                    | Sanofi-Aventis Cyprus Ltd          | Cyprus                                   |
| Triamlo                                 | SE/H/1339/001-005/DC                                                                  | 043405                                                                            | Zentiva Italia Srl                 | Italy                                    |

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| Impactin Duo                            | SE/H/1336/001-005                                                      | 20140180, 20140181, 20140182, 20140183,                               | Medica Ad                          | Bulgaria                                 |
| Ramizek                                 | SE/H/1336/001-005                                                      | 58/0026/15-S, 58/0027/15-S, 58/0028/15-S, 58/0029/15-S, 58/0030/15-S, | Adamed                             | Slovakia                                 |
| Ramdacordia                             |                                                                        | LT/1/12/2922/001-025                                                  | Sandoz Pharmaceuticals D.D.        | Lithuania                                |
| Ramipril/Amlodipine Apotex              | SE/H/1396/001/DC, SE/H/1396/002/DC, SE/H/1396/003/DC, SE/H/1396/004/DC | 50462, 50463, 50464, 50465                                            | Apotex Europe B.V.                 | Sweden                                   |
| Duoramix                                | SE/H/1396/001/DC, SE/H/1396/002/DC, SE/H/1396/003/DC, SE/H/1396/004/DC | 22101, 22102, 22103, 22104                                            | Apotex Europe B.V.                 | Poland                                   |