



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 June 2016  
EMA/377009/2016  
Procedure Management and Committees Support Division

## List of nationally authorised medicinal products

Active substance: metoclopramide

Procedure no.: PSUSA/00002036/201510



| <b>Product Name (in authorisation country)</b> | <b>MRP / DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b>                            | <b>Member State where product is authorised</b> |
|------------------------------------------------|---------------------------------------|--------------------------------------|----------------------------------------------------------------------|-------------------------------------------------|
| Anausin                                        |                                       | NL 14 480                            | Meda Pharma Sas                                                      | France                                          |
| Clopan                                         |                                       | 022889075                            | Fabbrica Italiana Ritrovati Medicinali Ed Affini F.I.R.M.A. - S.P.A. | Italy                                           |
| Degan                                          |                                       | 20/0161/87-C/S                       | Sandoz Pharmaceuticals D.D.                                          | Slovakia                                        |
| Degan                                          |                                       | 20/0162/87-C/S                       | Sandoz Pharmaceuticals D.D.                                          | Slovakia                                        |
| Dibertil                                       |                                       | 0430/11081248                        | Takeda Belgium Sca/Cva                                               | Luxembourg                                      |
| Dibertil                                       |                                       | 0430/11081249                        | Takeda Belgium Sca/Cva                                               | Luxembourg                                      |
| Dibertil                                       |                                       | BE129543                             | Takeda Belgium Sca/Cva                                               | Belgium                                         |
| Dibertil                                       |                                       | BE129552                             | Takeda Belgium Sca/Cva                                               | Belgium                                         |
| Maalox Nausea                                  |                                       | 033013020                            | Sanofi Spa                                                           | Italy                                           |
| Maalox Nausea                                  |                                       | 033013018                            | Sanofi Spa                                                           | Italy                                           |
| Mcp Abz                                        | DE-H-4152-001-DC                      | 92720.00.00                          | Abz-Pharma Gmbh                                                      | Germany                                         |
| Mcp-Ratiopharm                                 |                                       | 0687/01/08/6616                      | Ratiopharm Gmbh                                                      | Luxembourg                                      |
| Mcp-Ratiopharm                                 |                                       | 2009070405                           | Ratiopharm Gmbh                                                      | Luxembourg                                      |
| Mcp-Ratiopharm                                 |                                       | 3129.00.02                           | Ratiopharm Gmbh                                                      | Germany                                         |
| Mcp-Ratiopharm                                 |                                       | 6058726.00.00                        | Ratiopharm Gmbh                                                      | Germany                                         |
| Mcp-Ratiopharm                                 |                                       | 6608902.00.00                        | Ratiopharm Gmbh                                                      | Germany                                         |
| Mcp-Ratiopharm                                 | DE-H-4151-001-DC                      | 92719.00.00                          | Ratiopharm Gmbh                                                      | Germany                                         |
| Metoclopramide                                 |                                       | PL 00289/0192                        | Teva Uk Limited                                                      | United Kingdom                                  |
| Metoclopramide 10mg                            |                                       | PL 04556/0007                        | Pharmvit Limited                                                     | United Kingdom                                  |
| Paspertin                                      |                                       | 13.762                               | Bgp Products Ges. M. B. H.                                           | Austria                                         |
| Paspertin                                      |                                       | 13.764                               | Bgp Products Ges. M. B. H.                                           | Austria                                         |
| Paspertin                                      |                                       | 6168.00.00                           | Mylan Healthcare Gmbh                                                | Germany                                         |
| Paspertin                                      |                                       | 6168.00.01                           | Mylan Healthcare Gmbh                                                | Germany                                         |
| Plasil                                         |                                       | 020766010                            | Sanofi Spa                                                           | Italy                                           |

|           |  |                                        |                                     |            |
|-----------|--|----------------------------------------|-------------------------------------|------------|
| Plasil    |  | 020766022                              | Sanofi Spa                          | Italy      |
| Plasil    |  | 020766046                              | Sanofi Spa                          | Italy      |
| Primperan |  | 0093724                                | Sanofi Belgium                      | Luxembourg |
| Primperan |  | 0152131 \$ 0490187                     | Sanofi Belgium                      | Luxembourg |
| Primperan |  | 0152145                                | Sanofi Belgium                      | Luxembourg |
| Primperan |  | 05429                                  | Sanofi-Aventis Denmark A/S          | Denmark    |
| Primperan |  | 08653                                  | Sanofi Ab                           | Sweden     |
| Primperan |  | 08655                                  | Sanofi Ab                           | Sweden     |
| Primperan |  | 16090                                  | Sanofi-Aventis Cyprus Ltd           | Cyprus     |
| Primperan |  | 16093                                  | Sanofi-Aventis Cyprus Ltd           | Cyprus     |
| Primperan |  | 308 612-0 \$ 322 025-1<br>\$ 556 657-4 | Sanofi-Aventis France               | France     |
| Primperan |  | 308 614-3 \$ 322 029-7                 | Sanofi-Aventis France               | France     |
| Primperan |  | 316 953-8 \$ 323 179-2                 | Sanofi-Aventis France               | France     |
| Primperan |  | 40.256                                 | Sanofi-Aventis, S.A.                | Spain      |
| Primperan |  | 40.257                                 | Sanofi-Aventis, S.A.                | Spain      |
| Primperan |  | 41.446                                 | Sanofi-Aventis, S.A.                | Spain      |
| Primperan |  | 551 044-4                              | Sanofi-Aventis France               | France     |
| Primperan |  | 5815                                   | Sanofi Oy                           | Finland    |
| Primperan |  | 5816                                   | Sanofi Oy                           | Finland    |
| Primperan |  | 9138222 \$ 9138230                     | Sanofi - Produtos Farmaceuticos Lda | Portugal   |
| Primperan |  | 9138305                                | Sanofi - Produtos Farmaceuticos Lda | Portugal   |
| Primperan |  | 9138404                                | Sanofi - Produtos Farmaceuticos Lda | Portugal   |
| Primperan |  | BE036845                               | Sanofi Belgium                      | Belgium    |
| Primperan |  | BE036872                               | Sanofi Belgium                      | Belgium    |
| Primperan |  | BE036906                               | Sanofi Belgium                      | Belgium    |

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|--------------------------------------------------------|--|------------------------|-------------------------------------------|----------------|
| Primperan                                              |  | RVG 05251              | Sanofi-Aventis Netherlands B.V.           | Netherlands    |
| Primperan                                              |  | RVG 05252              | Sanofi-Aventis Netherlands B.V.           | Netherlands    |
| Primperan                                              |  | RVG 06013              | Sanofi-Aventis Netherlands B.V.           | Netherlands    |
| Primperan                                              |  | 321 694-7 \$ 321 695-3 | Sanofi-Aventis France                     | France         |
| Prokinyl L.P.                                          |  | NL 14386               | Techni-Pharma                             | France         |
| реглан                                                 |  | 20050444/06.12.2010    | Alkaloid Ltd                              | Bulgaria       |
| Primperan                                              |  | 32941/29/11-91         | Sanofi-Aventis Aebe                       | Greece         |
| Primperan                                              |  | 32936/29-11-91         | Sanofi-Aventis Aebe                       | Greece         |
| Primperan                                              |  | 32938/29-11-91         | Sanofi-Aventis Aebe                       | Greece         |
| Primperan                                              |  | 32939/29-11-91         | Sanofi-Aventis Aebe                       | Greece         |
| Maxolon 10mg Tablets                                   |  | PA 1142/11/3           | Amdipharm Limited                         | Ireland        |
| Metoclopramide 5mg/ml Solution for Injection           |  | PA 73/84/1             | Mercury Pharmaceuticals (Ireland) Limited | Ireland        |
| Maxolon 5 mg/ml Solution for Injection                 |  | PA 1142/11/1           | Amdipharm Limited                         | Ireland        |
| Metoclopramide 5mg/ml Solution for Injection           |  | PL 02848/0113          | Mercury Pharma International Limited      | United Kingdom |
| Maxolon High Dose                                      |  | PL 20072/0052          | Amdipharm UK Limited                      | United Kingdom |
| Maxolon Injection                                      |  | PL 20072/0051          | Amdipharm UK Limited                      | United Kingdom |
| Maxolon SR                                             |  | PL 20072/0047          | Amdipharm UK Limited                      | United Kingdom |
| Maxolon Tablets 10mg                                   |  | PL 20072/0048          | Amdipharm UK Limited                      | United Kingdom |
| Metoclopramide Injection 5mg/ml Solution for Injection |  | MA 079/00801           | Mercury Pharmaceuticals (Ireland) Limited | Malta          |
| Ceolat 1 mg/ml-Lösung zum Einnehmen                    |  | 135599                 | G.L. Pharma GmbH                          | Austria        |