



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 September 2021  
EMA/507606/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: lormetazepam

Procedure no.: PSUSA/00001910/202012



| <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> |
|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| LORAMET 1 mg comprimés                         | not available                       | BE 117661                            | MYLAN EPD BVBA/SPRL                       | BE                                              |
| LORAMET 1 mg comprimés                         | not available                       | 2010/050786                          | MYLAN EPD BVBA/SPRL                       | LU                                              |
| Loramet 1 mg comprimidos                       | not available                       | 56.293                               | MEDA PHARMA S.L.                          | ES                                              |
| LORAMET 1 mg tabletten                         | not available                       | BE 117661                            | MYLAN EPD BVBA/SPRL                       | BE                                              |
| LORAMET 1 mg Tabletten                         | not available                       | BE 117661                            | MYLAN EPD BVBA/SPRL                       | BE                                              |
| LORAMET 1 mg Tabletten                         | not available                       | 2010/050786                          | MYLAN EPD BVBA/SPRL                       | LU                                              |
| LORAMET 2 mg comprimés                         | not available                       | BE 123557                            | MYLAN EPD BVBA/SPRL                       | BE                                              |
| LORAMET 2 mg comprimés                         | not available                       | 2010/050787                          | MYLAN EPD BVBA/SPRL                       | LU                                              |
| Loramet 2 mg comprimidos                       | not available                       | 58.639                               | MEDA PHARMA S.L.                          | ES                                              |
| LORAMET 2 mg tabletten                         | not available                       | BE 123557                            | MYLAN EPD BVBA/SPRL                       | BE                                              |
| LORAMET 2 mg Tabletten                         | not available                       | BE 123557                            | MYLAN EPD BVBA/SPRL                       | BE                                              |
| LORAMET 2 mg Tabletten                         | not available                       | 2010/050787                          | MYLAN EPD BVBA/SPRL                       | LU                                              |
| Lormetazepam Apotex 2 mg, tabletten            | not available                       | RVG 24658                            | APOTEX EUROPE B.V.                        | NL                                              |
| Lormetazepam Kern Pharma 0,5 mg comprimidos    | ES/H/0189/001                       | 75.704                               | KERN PHARMA, S.L.                         | ES                                              |
| Lormetazepam Kern Pharma 0,5 mg comprimidos    | ES/H/0189/001                       | 75.704                               | KERN PHARMA, S.L.                         | ES                                              |
| Lormetazepam Tablets 0.5 mg                    | not available                       | PL 17225/0012                        | GENUS PHARMACEUTICALS HOLDINGS LIMITED    | XI                                              |
| Lormetazepam Tablets 1mg                       | not available                       | PL 17225/0013                        | GENUS PHARMACEUTICALS HOLDINGS LIMITED    | XI                                              |
| MINIAS 1 mg compresse rivestite                | not available                       | 023382017                            | BAYER SPA                                 | IT                                              |
| MINIAS 2 mg compresse rivestite                | not available                       | 023382031                            | BAYER SPA                                 | IT                                              |

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|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| MINIAS 2,5 mg/mL<br>gocce orali, soluzione     | not available                       | 023382029                            | BAYER SPA                                 | IT                                              |
| Noctamid - Tabletten                           | not available                       | 17.186                               | BAYER AUSTRIA GMBH                        | AT                                              |
| Noctamid 2,5 mg/ml<br>gotas orales en solución | not available                       | 63.332                               | TEOFARMA S.R.L.                           | ES                                              |
| NOCTAMIDE 1 mg,<br>comprimé sécable            | not available                       | 349 667-4                            | BAYER HEALTHCARE                          | FR                                              |
| NOCTAMIDE 1 mg,<br>comprimé sécable            | not available                       | 329 868-4                            | BAYER HEALTHCARE                          | FR                                              |
| NOCTAMIDE 2 mg,<br>comprimé sécable            | not available                       | 329 869-0                            | BAYER HEALTHCARE                          | FR                                              |
| NOCTAMIDE 2 mg,<br>comprimé sécable            | not available                       | 354 470-0                            | BAYER HEALTHCARE                          | FR                                              |
| NOCTAMIDE 2 mg,<br>comprimé sécable            | not available                       | 331 476-2                            | BAYER HEALTHCARE                          | FR                                              |
| SEDALAM® 2 mg/10 ml<br>Injektionslösung        | not available                       | 74788.00.00                          | DR. FRANZ KÖHLER CHEMIE<br>GMBH           | DE                                              |