



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 January 2017  
EMA/24845/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: clevidipine

Procedure no.: PSUSA/00010288/201605



| <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> |
|------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Cleviprex 0,5 mg/ml emulsiie voor injectie     | UK/H/2477/001                       | BE429852                             | THE MEDICINES COMPANY UK LTD              | BE                                              |
| Cleviprex 0,5 mg/ml emulsiie voor injectie     | UK/H/2477/001                       | BE429843                             | THE MEDICINES COMPANY UK LTD              | BE                                              |
| Cleviprex 0,5 mg/ml emulsión inyectable        | UK/H/2477/001                       | 76595                                | THE MEDICINES COMPANY UK LTD              | ES                                              |
| Cleviprex 0,5 mg/ml Emulsion zur Injektion     | UK/H/2477/001                       | 1-31403                              | THE MEDICINES COMPANY UK LTD              | AT                                              |
| Cleviprex 0,5 mg/ml Emulsion zur Injektion     | UK/H/2477/001                       | 77979.00.00                          | THE MEDICINES COMPANY UK LTD              | DE                                              |
| Cleviprex 0,5 mg/ml emulsione iniettabile      | UK/H/2477/001/DC                    | 041759010                            | THE MEDICINES COMPANY UK LTD              | IT                                              |
| Cleviprex 0,5 mg/ml emulsione iniettabile      | UK/H/2477/001/DC                    | 041759022                            | THE MEDICINES COMPANY UK LTD              | IT                                              |
| Cleviprex 0,5 mg/ml injektionsvätska, emulsion | UK/H/2477/001                       | 42321                                | THE MEDICINES COMPANY UK LTD              | SE                                              |
| Cleviprex 0,5 mg/ml, emulsie voor injectie     | UK/H/2477/001                       | RVG 104771                           | THE MEDICINES COMPANY UK LTD              | NL                                              |
| Cleviprex 0,5 mg/ml, émulsion injectable       | UK/H/2477/001                       | BE429852                             | THE MEDICINES COMPANY UK LTD              | BE                                              |
| Cleviprex 0,5 mg/ml, émulsion injectable       | UK/H/2477/001                       | BE429843                             | THE MEDICINES COMPANY UK LTD              | BE                                              |
| Cleviprex 0,5 mg/ml, émulsion injectable       | UK/H/2477/001                       | 219 977-3                            | THE MEDICINES COMPANY UK LTD              | FR                                              |
| Cleviprex 0,5 mg/ml, émulsion injectable       | UK/H/2477/001                       | 219 976-7                            | THE MEDICINES COMPANY UK LTD              | FR                                              |

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|------------------------------------------------|---------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Cleviprex 0,5 mg/ml, émulsion injectable       | UK/H/2477/001                         | 2013040085                           | THE MEDICINES COMPANY UK LTD              | LU                                              |
| Cleviprex 0.5 mg/ml emulsion for injection     | UK/H/2477/001                         | PL 16881/0003                        | THE MEDICINES COMPANY UK LTD              | UK                                              |