



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

2 September 2016  
EMA/600481/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance(s): cefotaxime

Procedure No.: PSUSA/00000599/201512



| 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 |
|----------------------------------------------------------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------------|
| Cefotaxim Mylan 2000 mg, poeder voor oplossing voor injectie of infusie    | NL/H/2208/003/DC             | RVG 108792                    | Mylan B.V.                         | NL                                       |
| Cefotaxim Mylan 500 mg, poeder voor oplossing voor injectie                | NL/H/2208/001/DC             | RVG 108786                    | Mylan B.V.                         | NL                                       |
| Cefotaxime FarmaPlus 1 g injektiokuiva-aine, liuostavarten                 | NL/H/2208/002/DC             | 29342                         | FARMAPLUS AS                       | FI                                       |
| Cefotaxime FarmaPlus 2 g pulver till injektions-/infusionsvätska, lösning. | NL/H/2208/002/DC             | 45323                         | FARMAPLUS AS                       | SE                                       |
| Cefotaxime Mylan                                                           | NL/H/2208/001/DC             | 21142                         | Mylan S.A.S.                       | PL                                       |
| CEFOTAXIME MYLAN 2 g, poudre pour solution injectable (IM - IV)            | not available                | NL 23 800                     | MYLAN S.A.S                        | FR                                       |
| Cefotaxime Mylan, 2 g, proszek do sporządzania roztworu do wstrzykiwań     | NL/H/2208/003                | 21144                         | MYLAN HOSPITAL AS                  | PL                                       |
| Claforan                                                                   | not available                | 8403                          | SANOFI-AVENTIS CYPRUS LTD          | CY                                       |
| CLAFORAN 0,5 g, poudre et solution pour solution injectable (IM-IV)        | not available                | 345 892-3                     | SANOFI-AVENTIS FRANCE              | FR                                       |
| CLAFORAN 0,5 g, poudre et solution pour solution injectable (IM-IV)        | not available                | 323 333-1                     | SANOFI-AVENTIS FRANCE              | FR                                       |
| Claforan 1 g por oldatos injekcióhoz vagy infúzióhoz                       | not available                | OGYI-T- 3724/01               | SANOFI-AVENTIS PRIVATE CO LTD      | HU                                       |
| CLAFORAN 1 g, poudre et solvant pour solution injectable (IM)              | not available                | 323 334-8                     | SANOFI-AVENTIS FRANCE              | FR                                       |
| CLAFORAN 1 g, poudre et solvant pour solution injectable (IV-IM)           | not available                | 323 332-5                     | SANOFI-AVENTIS FRANCE              | FR                                       |
| CLAFORAN 1 g, poudre et solvant pour solution injectable (IV-IM)           | not available                | 345 894-6                     | SANOFI-AVENTIS FRANCE              | FR                                       |
| CLAFORAN 1 g, poudre et solvant pour solution injectable (IV-IM)           | not available                | 330 709-3                     | SANOFI-AVENTIS FRANCE              | FR                                       |
| Claforan 1000 mg poeder en oplosmiddel voor oplossing voor injectie        | not available                | BE116383                      | SANOFI BELGIUM                     | BE                                       |
| Claforan 1000 mg poudre et solvant pour solution injectable                | not available                | BE116383                      | SANOFI BELGIUM                     | BE                                       |

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|----------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Claforan 1000 mg poudre et solvant pour solution injectable                | not available                       | 1800/03037192                        | SANOFI BELGIUM                            | LU                                              |
| CLAFORAN 2 G, POUDRE POUR SOLUTION INJECTABLE (I.M./I.V.)                  | not available                       | 562 423-1                            | SANOFI-AVENTIS FRANCE                     | FR                                              |
| CLAFORAN 2 G, POUDRE POUR SOLUTION INJECTABLE (I.M./I.V.)                  | not available                       | 562 424-8                            | SANOFI-AVENTIS FRANCE                     | FR                                              |
| CLAFORAN 2 g/10 ml, poudre et solvant pour solution injectable (I.M./I.V.) | not available                       | 562 425-4                            | SANOFI-AVENTIS FRANCE                     | FR                                              |
| Claforan 2000 mg poeder en oplosmiddel voor oplossing voor injectie        | not available                       | BE116392                             | SANOFI BELGIUM                            | BE                                              |
| CLAFORAN 2000 MG POEDER EN OPLOSMIDDEL VOOR OPLOSSING VOOR INJECTIE        | not available                       | BE116392                             | SANOFI-AVENTIS BELGIUM                    | BE                                              |
| Claforan 2000 mg poeder voor oplossing voor infusie                        | not available                       | BE205773                             | SANOFI BELGIUM                            | BE                                              |
| Claforan 2000 mg poudre et solvant pour solution injectable                | not available                       | BE116392                             | SANOFI BELGIUM                            | BE                                              |
| Claforan 2000 mg poudre et solvant pour solution injectable                | not available                       | 1800/03037191                        | SANOFI BELGIUM                            | LU                                              |
| Claforan 2000 mg poudre pour solution pour perfusion                       | not available                       | BE205773                             | SANOFI BELGIUM                            | BE                                              |
| Claforan 2000 mg poudre pour solution pour perfusion                       | not available                       | 1800/03037192                        | SANOFI BELGIUM                            | LU                                              |
| Claforan Powder for Solution for Injection 1g                              | not available                       | PA 540/37/3                          | SANOFI-AVENTIS IRELAND LTD                | IE                                              |
| Claforan Powder for Solution for Injection 500mg                           | not available                       | PA 540/37/2                          | SANOFI-AVENTIS IRELAND LTD                | IE                                              |
| Claforan pulver till injektions-/infusionsvätska, lösning                  | not available                       | 20547                                | SANOFI AB                                 | SE                                              |
| Claforan pulver till injektionsvätska, lösning                             | not available                       | 9820                                 | SANOFI AB                                 | SE                                              |
| Claforan pulver till injektionsvätska, lösning                             | not available                       | 9820                                 | SANOFI AB                                 | SE                                              |
| Claforan, poeder voor oplossing voor injectie 1000 mg                      | not available                       | RVG 08649                            | SANOFI-AVENTIS NETHERLANDS B.V.           | NL                                              |
| Claforan, poeder voor oplossing voor injectie 250 mg                       | not available                       | RVG 08647                            | SANOFI-AVENTIS NETHERLANDS B.V.           | NL                                              |

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| Claforan® 0,5 g Pulver mit Lösungsmittel zur Herstellung einer Injektionslösung                               | not available                | 6715.00.00                    | SANOFI-AVENTIS DEUTSCHLAND GMBH    | DE                                       |
| CLAFORAN® 0,5 g/VIAL (IV+IM), Κόνις για ενέσιμο διάλυμα                                                       | not available                | 175970101                     | SANOFI-AVENTIS AEBE                | GR                                       |
| CLAFORAN® 1 g/VIAL (IV), Κόνις για ενέσιμο διάλυμα                                                            | not available                | 175970301                     | SANOFI-AVENTIS AEBE                | GR                                       |
| Claforan® 1,0 g Pulver (bzw. Pulver mit Lösungsmittel) zur Herstellung einer Injektions- bzw. Infusionslösung | not available                | 6715.01.00                    | SANOFI-AVENTIS DEUTSCHLAND GMBH    | DE                                       |
| Claforan® 2,0 g Pulver (bzw. Pulver mit Lösungsmittel) zur Herstellung einer Injektions- bzw. Infusionslösung | not available                | 6715.02.00                    | SANOFI-AVENTIS DEUTSCHLAND GMBH    | DE                                       |
| ClaforanTM Injection 1g                                                                                       | not available                | PL 04425/0188                 | AVENTIS PHARMA LTD                 | UK                                       |
| ClaforanTM Injection 250mg                                                                                    | not available                | PL 04425/0188                 | AVENTIS PHARMA LTD                 | UK                                       |
| ClaforanTM Injection 2g                                                                                       | not available                | PL 04425/0188                 | AVENTIS PHARMA LTD                 | UK                                       |
| ClaforanTM Injection 500mg                                                                                    | not available                | PL 04425/0188                 | AVENTIS PHARMA LTD                 | UK                                       |
| SALOCF 1 g - polvere e solvente per soluzione iniettabile i.m./e.v.                                           | not available                | 035285030                     | NEW RESEARCH SRL                   | IT                                       |
| SALOCF 1 g - polvere e solvente per soluzione iniettabile per uso intramuscolare                              | not available                | 035285042                     | NEW RESEARCH SRL                   | IT                                       |
| Zariviz 1 g/4 ml polvere e solvente per soluzione iniettabile                                                 | not available                | 024259032                     | SANOFI SPA                         | IT                                       |
| Zariviz 1 g/4 ml polvere e solvente per soluzione iniettabile per uso intramuscolare                          | not available                | 024259044                     | SANOFI SPA                         | IT                                       |
| Zariviz 2 g/10 ml polvere e solvente per soluzione iniettabile per uso endovenoso                             | not available                | 024259069                     | SANOFI SPA                         | IT                                       |
| Zariviz 500 mg/2 ml polvere e solvente per soluzione iniettabile                                              | not available                | 024259020                     | SANOFI SPA                         | IT                                       |