



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

11 July 2019  
EMA/403947/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: cefotaxime

Procedure no.: PSUSA/00000599/201812

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<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>
CEFOTAXIME MYLAN 2 g, poudre pour solution injectable (IM - IV)	not available	NL23800	MYLAN S.A.S	FR
Cefotaxima Hikma, 500 mg, Pó e solvente para solução injectável, IM/IV	not available	2440295	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 500 mg, Pó e solvente para solução injectável, IM/IV	not available	2220291	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 500 mg, Pó e solvente para solução injectável, IM/IV	not available	4686192	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 500 mg, Pó e solvente para solução injectável, IM/IV	not available	2440394	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IM	not available	2440493	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IM	not available	2421196	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IM	not available	2220390	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IM	not available	4686291	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT

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Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IV	not available	4686390	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IV	not available	2422491	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IV	not available	2440592	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxima Hikma, 1000 mg, Pó e solvente para solução injectável, IV	not available	2220499	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Cefotaxim MIP 2 g por oldatos injekcióhoz vagy infúzióhoz	DK/H/2158/002	OGYI-T-22518/04	MIP PHARMA GMBH	HU
Cefotaxim MIP 2 g por oldatos injekcióhoz vagy infúzióhoz	DK/H/2158/002	OGYI-T-22518/05	MIP PHARMA GMBH	HU
Cefotaxim MIP 2 g por oldatos injekcióhoz vagy infúzióhoz	DK/H/2158/002	OGYI-T-22518/06	MIP PHARMA GMBH	HU
Zariviz 1 g/4 ml polvere e solvente per soluzione iniettabile	not available	024259032	SANOFI S.P.A	IT
SALOCEF 1 g - polvere e solvente per soluzione iniettabile i.m./e.v.	not available	035285030	NEW RESEARCH SRL	IT

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SALOCEF 1 g - polvere e solvente per soluzione iniettabile per uso intramuscolare	not available	035285042	NEW RESEARCH SRL	IT
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
Claforan 0,5 g Pulver mit Lösungsmittel zur Herstellung einer Injektionslösung	not available	6715.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Claforan	not available	8403	SANOFI-AVENTIS CYPRUS LTD	CY
CLAFORAN 1000	not available	0006/00/07/5950	SANOFI BELGIUM	LU
CLAFORAN 1000	not available	22459	SANOFI BELGIUM	LU
CLAFORAN 1000	not available	0206716	SANOFI BELGIUM	LU
Claforan 1,0 g Pulver (bzw. Pulver mit Lösungsmittel) zur	not available	6715.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE

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Herstellung einer Injektions- bzw. Infusionslösung				
CLAFORAN 1 G POR OLDATOS INJEKCIHOZ	not available	OGYI-T-3724/01	SANOFI-AVENTIS ZRT	HU
CLAFORAN® 1 g/VIAL (IV), Κόνις για ενέσιμο διάλυμα	not available	175970301	SANOFI-AVENTIS AEBE	GR
CLAFORAN® 1 g/VIAL (IV), Κόνις για ενέσιμο διάλυμα	not available	175970302	SANOFI-AVENTIS AEBE	GR
CLAFORAN 250	not available	RVG 08647	SANOFI-AVENTIS NETHERLANDS B.V.	NL
CLAFORAN 1000	not available	RVG 08649	SANOFI-AVENTIS NETHERLANDS B.V.	NL
CLAFORAN 1000	not available	RVG 08649	SANOFI-AVENTIS NETHERLANDS B.V.	NL
CLAFORAN 250	not available	RVG 08647	SANOFI-AVENTIS NETHERLANDS B.V.	NL
CLAFORAN 0.5 G IV-IM	not available	345 892 3	SANOFI-AVENTIS FRANCE	FR

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CLAFORAN 1 G IV-IM	not available	323 332-5	SANOFI-AVENTIS FRANCE	FR
CLAFORAN 1 G IV-IM	not available	345 894-6	SANOFI-AVENTIS FRANCE	FR
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 0.5 G IV-IM	not available	323 333-1	SANOFI-AVENTIS FRANCE	FR
CLAFORAN 1 G IV-IM	not available	330 709-3	SANOFI-AVENTIS FRANCE	FR
CLAFORAN 2 g/10 ml, poudre et solvant pour solution injectable (IM-IV)	not available	562 425-4	SANOFI-AVENTIS FRANCE	FR
Claforan 1000 mg poudre et solvant pour solution injectable	not available	BE116383	SANOFI BELGIUM	BE
Claforan 1000 mg poeder en oplossing voor injectie	not available	BE116383	SANOFI BELGIUM	BE

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Claforan Powder for Solution for Injection 500mg	not available	PA 540/37/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Claforan Powder for Solution for Injection 500mg	not available	PA 540/37/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Claforan Powder for Solution for Injection 1g	not available	PA 540/37/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Claforan Powder for Solution for Injection 1g	not available	PA 540/37/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Claforan Powder for Solution for Injection 500mg	not available	PA 540/37/2	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Claforan Powder for Solution for Injection 1g	not available	PA 540/37/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Cefotaxim Sandoz 0,5 g, poeder voor oplossing voor injectie	AT/H/0278/001	RVG 27756	SANDOZ B.V.	NL