EMA/PRAC/773016/2017
Pharmacovigilance Risk Assessment Committee (PRAC)

PRAC PSUR assessment report

Active substance(s): cefuroxime sodium (except for intracameral use)

Procedure No.: PSUSA/00000615/201704

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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
Cefuroxim „Astro“ - 1,5 g Trockensubstanz zur Infusionsbereitung	not available	1-22177	ASTRO-PHARMA GMBH	AT
Cefuroxim „Astro“ - Trockenstechampulle	not available	1-22175	ASTRO-PHARMA GMBH	AT
Cefuroxim Hikma 1500 mg, Poeder voor injectie I.V.	not available	RVG20590	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	NL
Cefuroxim Hikma 750 mg, Poeder voor injectie I.V. / I.M	not available	RVG20588	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	NL
CEFUROXIMA SANDOZ	NL/H/0560/002	5468681	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468988	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5469085	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468780	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5469184	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468889	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468681	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468988	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5469085	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468780	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5469184	SANDOZ FARMACÊUTICA LDA.	PT
CEFUROXIMA SANDOZ	NL/H/0560/002	5468889	SANDOZ FARMACÊUTICA LDA.	PT
Curocef 1500 mg Pulver zur Herstellung einer Injektions- oder Infusionslösung	NO/H/0235/03	16.569	GLAXOSMITHKLINE PHARMA GMBH.	AT
Curocef® 1500 mg Pulver zur Herstellung einer Infusionslösung in einer Einzelampulle	IT/H/347/07	16.570	GLAXOSMITHKLINE PHARMA GMBH.	AT
Curoxim 1 g polvere e solvente per soluzione iniettabile	IT/H/0347/005	023576059	GLAXOSMITHKLINE S.P.A.	IT
Curoxim 1 g polvere e solvente per sospensione iniettabile	IT/H/0347/004	023576046	GLAXOSMITHKLINE S.P.A.	IT
Curoxim 1,5 g polvere per soluzione per infusione (con dispositivo Monovial)	IT/H/0347/007	023576097	GLAXOSMITHKLINE S.P.A.	IT
Curoxim 2 g polvere per soluzione	IT/H/0347/008	023576061	GLAXOSMITHKLINE S.P.A.	IT

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
per infusione				
Curoxim 250 mg polvere e solvente per sospensione iniettabile	IT/H/0347/001	023576010	GLAXOSMITHKLINE S.P.A.	IT
Curoxim 500 mg polvere e solvente per sospensione iniettabile	IT/H/0347/002	023576022	GLAXOSMITHKLINE S.P.A.	IT
Curoxim 750 mg polvere e solvente per sospensione iniettabile	IT/H/0347/003	023576034	GLAXOSMITHKLINE S.P.A.	IT
Curoxim 750 mg polvere per soluzione per infusione (con dispositivo Monovial)	IT/H/0347/006	023576085	GLAXOSMITHKLINE S.P.A.	IT
Kefurox 1500 mg, poeder voor oplossing voor injectie of infusie	not available	BE201591	EUROCEPT B.V.	BE
Kefurox 1500 mg, poudre pour solution injectable ou pour perfusion	not available	BE201591	EUROCEPT B.V.	BE
Kefurox 1500 mg, poudre pour solution injectable ou pour perfusion	not available	2006038449	EUROCEPT B.V.	LU
Kefurox 1500 mg, Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	BE201591	EUROCEPT B.V.	BE
Kefurox 1500 mg, Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	2006038449	EUROCEPT B.V.	LU
Kefurox 750 mg, poeder voor oplossing voor injectie of infusie	not available	BE201582	EUROCEPT B.V.	BE
Kefurox 750 mg, poudre pour solution injectable ou pour perfusion	not available	BE201582	EUROCEPT B.V.	BE
Kefurox 750 mg, poudre pour solution injectable ou pour perfusion	not available	2006038448	EUROCEPT B.V.	LU

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
Kefurox 750 mg, Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	BE201582	EUROCEPT B.V.	BE
Kefurox 750 mg, Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	2006038448	EUROCEPT B.V.	LU
Zinacef	IT/H/347/07	10531	GLAXOSMITHKLINE PHARMA A/S	DK
Zinacef	NO/H/0235/02	09736	GLAXOSMITHKLINE PHARMA A/S	DK
Zinacef	NO/H/0235/003	09737	GLAXOSMITHKLINE PHARMA A/S	DK
ZINACEF	NO/H/0235/002	38979/10/18-4-11	GLAXOSMITHKLINE AEBE	GR
Zinacef 1,5 g injektio-/infuusiokuiva-aine, liuosta varten	NO/H/0235/003	7830	GLAXOSMITHKLINE OY	FI
Zinacef 1,5 g milteliai injekciniam tirpalui	NO/H/0235/03	LT/1/94/0179/001	GLAXO OPERATIONS UK LTD	LT
Zinacef 1,5 g poeder voor oplossing voor infusie (in Monovial)	NO/H/0235/003	BE113172	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 1,5 g poeder voor oplossing voor infusie (in Monovial)	IT/H/0347/007	2008 01 9628	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 1,5 g poeder voor oplossing voor injectie	NO/H/0235/003	BE168156	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 1,5 g poeder voor oplossing voor injectie	NO/H/0235/003	2008 01 9629	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 1,5 g por oldatos injekcióhoz vagy infúzióhoz	NO/H/0235/003	OGYI-T-1091/01	GLAXOSMITHKLINE KFT.	HU
Zinacef 1,5 g poudre pour solution pour perfusion (présentation Monovial)	IT/H/347/07	BE113172	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 1,5 g poudre pour solution pour perfusion (présentation Monovial)	IT/H/347/07	2008 01 9628	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 1,5 g prášek pro injekční/infuzní roztok	NO/H/0235/03	15/171/81-B/C	GLAXO GROUP LIMITED	CZ
Zinacef 1,5 g pulver til injeksjons-	NO/H/0235/003	11-8522	GLAXOSMITHKLINE AS	NO

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/infusjonsvæske				
Zinacef 1,5 g pulver till injektions- eller infusionsvätska, lösning	NO/H/0235/003	7830	GLAXOSMITHKLINE OY	FI
Zinacef 1,5 g pulver till injektions- /infusionsvätska, lösning	NO/H/0235/003	51399	GLAXOSMITHKLINE AB	SE
Zinacef 1,5 g Pulver zur Herstellung einer Infusionslösung (Monovial)	NO/H/0235/003	BE113172	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 1,5 g Pulver zur Herstellung einer Infusionslösung (Monovial)	IT/H/0347/007	2008 01 9628	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 1,5 g Pulver zur Herstellung einer Injektionslösung	NO/H/0235/003	BE168156	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 1,5 g Pulver zur Herstellung einer Injektionslösung	NO/H/0235/003	2008 01 9629	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 1,5 g stungulyfs- /innrennslisstofn, lausn	NO/H/0235/003	802630 (IS)	GLAXOSMITHKLINE PHARMA A/S	IS
Zinacef 1,5 g, poudre pour solution injectable	NO/H/0235/03	BE168156	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 1,5 g, poudre pour solution injectable	NO/H/0235/03	2008 01 9629	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 1500 mg prašek za raztopino za injiciranje/infundiranje	NO/H/0235/03	H/93/01702/002	GLAXOSMITHKLINE D.O.O.	SI
Zinacef 250 mg injektio- /infuusiokuiva-aine, liuosta varten	NO/H/0235/001	31236	GLAXOSMITHKLINE OY	FI
Zinacef 250 mg milteliai ir tirpiklis injekciniam tirpalui	IT/H/347/01	LT/1/94/0179/003	GLAXO OPERATIONS UK LTD	LT
Zinacef 250 mg milteliai ir tirpiklis injekciniam tirpalui	NO/H/0235/001	LT/1/94/0179/003	GLAXO OPERATIONS UK LTD	LT
Zinacef 250 mg por és oldószer oldatos injekcióhoz	IT/H/347/01	OGYI-T-1086/01	GLAXOSMITHKLINE KFT.	HU
Zinacef 250 mg por oldatos injekcióhoz vagy infúzióhoz	NO/H/0235/001	OGYI-T-6157/01	GLAXOSMITHKLINE KFT.	HU
Zinacef 250 mg por oldatos	NO/H/0235/001	OGYI-T-6157/02	GLAXOSMITHKLINE KFT.	HU

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injekcióhoz vagy infúzióhoz				
Zinacef 250 mg powder for solution for injection	NO/H/0235/001	MA169/00201	GLAXO OPERATIONS UK LTD	MT
Zinacef 250 mg pulver til injeksjons-/infusjonsvæske	NO/H/0235/001	00-6664	GLAXOSMITHKLINE AS	NO
Zinacef 250 mg pulver till injektions- eller infusionsvätska, lösning	NO/H/0235/001	31236	GLAXOSMITHKLINE OY	FI
Zinacef 250 mg pulver till injektions-/infusionsvätska, lösning	NO/H/0235/01	50970	GLAXOSMITHKLINE AB	SE
Zinacef 750 mg injektio-/infuusiokuiva-aine, liuosta varten	NO/H/0235/002	31237	GLAXOSMITHKLINE OY	FI
Zinacef 750 mg milteliai ir tirpiklis injekciniam tirpalui	IT/H/347/03	LT/1/94/0179/002	GLAXO OPERATIONS UK LTD	LT
Zinacef 750 mg poeder voor oplossing voor injectie	NO/H/0235/002	BE168147	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 750 mg poeder voor oplossing voor injectie	NO/H/0235/002	2008 01 9626	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 750 mg por és oldószer oldatos injekcióhoz	IT/H/347/03	OGYI-T-1087/01	GLAXOSMITHKLINE KFT.	HU
Zinacef 750 mg por oldatos injekcióhoz vagy infúzióhoz	NO/H/0235/002	OGYI-T 6158/01	GLAXOSMITHKLINE KFT.	HU
Zinacef 750 mg por oldatos injekcióhoz vagy infúzióhoz	NO/H/0235/002	OGYI-T-6158/02	GLAXOSMITHKLINE KFT.	HU
Zinacef 750 mg powder for solution for injection	NO/H/0235/002	MA 169/00202	GLAXO OPERATIONS UK LTD	MT
Zinacef 750 mg prášek pro injekcní/infuzní roztok	NO/H/0235/02	15/171/81-A/C	GLAXO GROUP LIMITED	CZ
Zinacef 750 mg prašek za raztopino za injiciranje/infundiranje	NO/H/0235/002	H/93/01702/001	GLAXOSMITHKLINE D.O.O.	SI
Zinacef 750 mg pulver til injeksjons-/infusjonsvæske	NO/H/0235/002	11-8521	GLAXOSMITHKLINE AS	NO
Zinacef 750 mg pulver till	NO/H/0235/002	31237	GLAXOSMITHKLINE OY	FI

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injektions- eller infusionsvätska, lösning				
Zinacef 750 mg pulver till injektions-/infusionsvätska, lösning	NO/H/0235/02	50971	GLAXOSMITHKLINE AB	SE
Zinacef 750 mg Pulver zur Herstellung einer Injektionslösung	NO/H/0235/002	BE168147	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 750 mg Pulver zur Herstellung einer Injektionslösung	NO/H/0235/002	2008 01 9626	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef 750 mg stungulyfs-/innrennslisstofn, lausn	NO/H/0235/002	802629 (IS)	GLAXOSMITHKLINE PHARMA A/S	IS
Zinacef 750 mg, poudre pour solution injectable	NO/H/0235/02	BE168147	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Zinacef 750 mg, poudre pour solution injectable	NO/H/0235/02	2008 01 9626	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Zinacef for Injection or Infusion	IT/H/347/07	PL 00004/0263	GLAXO OPERATIONS UK LTD	UK
Zinacef for Injection or Infusion	NO/H/0235/02	PL 00004/0263	GLAXO OPERATIONS UK LTD	UK
Zinacef for Injection or Infusion	NO/H/0235/03	PL 00004/0263	GLAXO OPERATIONS UK LTD	UK
Zinacef for Injection or Infusion	IT/H/347/06	PL 00004/0263	GLAXO OPERATIONS UK LTD	UK
Zinacef for Injection or Infusion	NO/H/0235/01	PL 00004/0263	GLAXO OPERATIONS UK LTD	UK
Zinacef κόνις για ενέσιμο διάλυμα ή διάλυμα προς έγχυση 1,5 g	NO/H/0235/003	19520	GLAXO GROUP LIMITED	CY
Zinacef κόνις για ενέσιμο διάλυμα ή διάλυμα προς έγχυση 750 mg	NO/H/0235/002	19521	GLAXO GROUP LIMITED	CY
Zinacef, 1,5 g süste- või infusioonilahuse pulber	NO/H/0235/03	226298	GLAXO GROUP LIMITED	EE
Zinacef, 1500 mg, proszek do sporządzania roztworu do wstrzykiwań lub infuzji	NO/H/0235/003	R/0699	GLAXOSMITHKLINE EXPORT LTD	PL
Zinacef, 750 mg süste- või infusioonilahuse pulber	NO/H/0235/02	226198	GLAXO GROUP LIMITED	EE
Zinacef, 750 mg, proszek do sporządzania roztworu do wstrzykiwań lub infuzji	NO/H/0235/02	R/0698	GLAXOSMITHKLINE EXPORT LTD	PL
Zinacef® 1.5 g powder for	NO/H/0235/003	PA 1077/14/3	GLAXOSMITHKLINE (IRELAND)	IE

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
solution for injection or infusion			LIMITED	
Zinacef® 250 mg powder for solution or suspension for injection	NO/H/0235/001	PA 1077/14/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Zinacef® 750 mg powder for solution or suspension for injection	NO/H/0235/002	PA 1077/14/2	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Zinacef® Hikma 1500 mg Pulver [ggf. mit Lösungsmittel] zur Herstellung einer Injektions- oder Infusionslösung	not available	334.04.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Zinacef® Hikma 250 mg Pulver [ggf. mit Lösungsmittel] zur Herstellung einer Injektionslösung	not available	334.00.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
Zinacef® Hikma 750 mg Pulver [ggf. mit Lösungsmittel] zur Herstellung einer Injektionslösung	not available	334.03.00	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	DE
ZINNAT 1,5 g, poudre pour solution pour perfusion	NO/H/0235/03	VNL11555	LABORATOIRE GLAXOSMITHKLINE	FR
ZINNAT 250 mg, poudre pour solution injectable (I.M., I.V.)	NO/H/0235/001	VNL11556-2	LABORATOIRE GLAXOSMITHKLINE	FR
ZINNAT 750 mg, poudre et solvant pour suspension injectable (I.M.)	IT/H/347/03	VNL11558-1	LABORATOIRE GLAXOSMITHKLINE	FR
ZINNAT 750 mg, poudre pour solution injectable (I.M., I.V.)	NO/H/0235/02	VNL11558-2	LABORATOIRE GLAXOSMITHKLINE	FR