30 January 2019
EMA/226028/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Cefuroxime sodium (for intracameral use)

Procedure no.: PSUSA/00010206/201805

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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
APROKAM 50 mg prášok na injekčný roztok	SE/H/1080/001	15/0391/12-S	LABORATOIRES THEA	SK
APROKAM 50 mg, pulbere pentru soluţie injectabilă	SE/H/1080/001	10108/2017/02	LABORATOIRES THEA	RO
APROKAM 50 mg, pulbere pentru soluţie injectabilă	SE/H/1080/001	10108/2017/03	LABORATOIRES THEA	RO
APROKAM 50 mg, poudre pour solution injectable	SE/H/1080/001	34009 550 285 1 2	LABORATOIRES THEA	FR
Aprokam 50 mg polvere per soluzione iniettabile	SE/H/1080/001	042048049	LABORATOIRES THEA	IT
Aprokam 50 mg poudre pour solution injectable	SE/H/1080/001	BE422457	LABORATOIRES THEA	BE
Aprokam 50 mg poeder voor oplossing voor injectie	SE/H/1080/001	BE422457	LABORATOIRES THEA	BE
APROKAM 50 mg stungulyfsstofn, lausn til inndælingar í augnhólf	SE/H/1080/001	IS/1/12/066/01	LABORATOIRES THEA	IS
Aprokam 50 mg Pulver zur Herstellung einer Injektionslösung	SE/H/1080/001	1-31360	LABORATOIRES THEA	AT

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
APROKAM 50 mg pó para solução injetável	SE/H/1080/001	5466248	LABORATOIRES THEA	PT
APROKAM 50 mg pó para solução injetável	SE/H/1080/001	5466255	LABORATOIRES THEA	PT
АПРОКАМ 50 mg прах за инжекционен разтвор	SE/H/1080/001	20120368	LABORATOIRES THEA	BG
Aprokam 50 mg pulver til injeksjonsvæske, oppløsning	SE/H/1080/001	MTNR 11-8345	LABORATOIRES THEA	NO
Aprokam 50 mg pulver till injektionsvätska, lösning	SE/H/1080/001	46149	LABORATOIRES THEA	SE
APROKAM 50 mg, poudre pour solution injectable	SE/H/1080/001	34009 224 104 4 9	LABORATOIRES THEA	FR
APROKAM 50 mg, poudre pour solution injectable	SE/H/1080/001	34009 582 956 5 2	LABORATOIRES THEA	FR
APROKAM 50 mg, poudre pour solution injectable	SE/H/1080/001	34009 582 957 1 3	LABORATOIRES THEA	FR
Aprokam 50 mg prašek za raztopino za injiciranje	SE/H/1080/01	H/12/00206/003	LABORATOIRES THEA	SI

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
Aprokam 50 mg prašek za raztopino za injiciranje	SE/H/1080/01	H/12/00206/004	LABORATOIRES THEA	SI
APROKAM 50 mg pulbere pentru soluţie injectabilă	SE/H/1080/001	10108/2017/04	LABORATOIRES THEA	RO
Aprokam, pulver til injektionsvæske, opløsning	SE/H/1080/001	48940	LABORATOIRES THEA	DK
APROKAM, 50 mg, proszek do sporzadzania roztworu do wstrzykiwan	SE/H/1080/001	20642	LABORATOIRES THEA	PL
APROKAM 50 mg powder for solution for injection	SE/H/1080/001	PL 20162/0014	LABORATOIRES THEA	UK
APROKAM 50 mg, pulbere pentru soluţie injectabilă	SE/H/1080/001	10108/2017/01	LABORATOIRES THEA	RO
Aprok 50 mg powder for solution for injection	SE/H/1080/001	PA1107/006/001	LABORATOIRES THEA	IE
Aprokam 50 mg poeder voor oplossing voor injectie	SE/H/1080/001	RVG 109659	LABORATOIRES THEA	NL
Aprokam 50 mg injektiokuiva-aine, liuosta varten	SE/H/1080/001	MTNR 29830	LABORATOIRES THEA	FI

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
Prokam 50 mg polvo para solución inyectable	SE/H/1080/001	76098	LABORATOIRES THEA	ES
Aprokam 50 mg Pulver zur Herstellung einer Injektionslösung	SE/H/1080/001	84940.00.00	LABORATOIRES THEA	DE
Aprokam 50 mg polvere per soluzione iniettabile	SE/H/1080/001	042048013	LABORATOIRES THEA	IT
Aprokam 50 mg polvere per soluzione iniettabile	SE/H/1080/001	042048025	LABORATOIRES THEA	IT
Aprokam 50 mg prášek pro injekční roztok	SE/H/1080/001	64/535/12-C	LABORATOIRES THEA	CZ
Aprokam 50 mg prašek za raztopino za injiciranje	SE/H/1080/001	H/12/00206/001	LABORATOIRES THEA	SI
Aprokam 50 mg prašek za raztopino za injiciranje	SE/H/1080/001	H/12/00206/002	LABORATOIRES THEA	SI
PROKAM 50 mg κόνις για ενέσιμο διάλυμα	SE/H/1080/001	021674	LABORATOIRES THEA	CY
Aprokam 50 mg poudre pour solution injectable	SE/H/1080/001	2013040077	LABORATOIRES THEA	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
PROKAM 50 mg κόνις για ενέσιμο διάλυμα	SE/H/1080/01/DC	34569/30-4-2013	LABORATOIRES THEA	GR
Ximaract 50 mg powder for solution for injection	SE/H/1494/001	PL 33616/0024	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	UK
Ximaract 50 mg poudre pour solution injectable	SE/H/1494/001	BE498613	BAUSCH & LOMB PHARMA	BE
Ximaract 50 mg poeder voor oplossing voor injectie	SE/H/1494/001	BE498613	BAUSCH & LOMB PHARMA	BE
Ximaract 50 mg Pulver zur Herstellung einer Injektionslösung	SE/H/1494/001	94541.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ximaract 50 mg Pulver zur Herstellung einer Injektionslösung	SE/H/1494/001	137106	BAUSCH & LOMB GMBH	AT
Ximaract, 50 mg süstelahuse pulber	SE/H/1494/001	919516	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Ximaract 50 mg poeder voor oplossing voor injectie	SE/H/1494/001	RVG 117330	BAUSCH & LOMB PHARMA	NL
Ximaract 50 mg por oldatos injekcióhoz	SE/H/1494/001	OGYI-T-23080/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU

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
Ximaract 50 mg por oldatos injekcióhoz	SE/H/1494/001	OGYI-T-23080/02	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Ximaract 50 mg por oldatos injekcióhoz	SE/H/1494/001	OGYI-T-23080/03	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Ximaract 50 mg por oldatos injekcióhoz	SE/H/1494/001	OGYI-T-23080/04	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Ximaract 50 mg por oldatos injekcióhoz	SE/H/1494/001	OGYI-T-23080/05	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Ximaract 50 mg por oldatos injekcióhoz	SE/H/1494/001	OGYI-T-23080/06	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
Ximaract 50 mg prášok na injekčný roztok	SE/H/1494/001	64/0406/16-S	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SK
Ximaract 50 mg polvo para solución inyectable	SE/H/1494/001	713478	BAUSCH & LOMB, S.A.	ES
Ximaract 50 mg polvo para solución inyectable	SE/H/1494/001	606788	BAUSCH & LOMB, S.A.	ES
Ximaract 50 mg milteliai injekciniam tirpalui	SE/H/1494/001	LT/1/16/3976/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT

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
Ximaract 50 mg milteliai injekciniam tirpalui	SE/H/1494/001	LT/1/16/3976/002	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Ximaract 50 mg milteliai injekciniam tirpalui	SE/H/1494/001	LT/1/16/3976/003	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Ximaract 50 mg polvere per soluzione iniettabile	SE/H/1494/001	044417018	BAUSCH & LOMB IOM S.P.A	IT
Ximaract 50 mg polvere per soluzione iniettabile	SE/H/1494/001	044417020	BAUSCH & LOMB IOM S.P.A	IT
Ximaract 50 mg polvere per soluzione iniettabile	SE/H/1494/001	044417032	BAUSCH & LOMB IOM S.P.A	IT
Ximaract 50 mg pó para solução injectável	SE/H/1494/001	SE/H/1494/001	BAUSCH & LOMB, S.A.	PT
Ксимаракт 50 mg прах за инжекционен разтвор	SE/H/1494/001	20170014	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
Ximaract, 50 mg, proszek do sporządzania roztworu do wstrzykiwań	SE/H/1494/001	23779	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Ximaract 50 mg pulver till injektionsvätska, lösning	SE/H/1494/001	52911	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SE

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
Ximaract 50 mg pulver til injeksjonsvæske, oppløsnng	SE/H/1494/001	15-10680	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	NO
ICECA 50 mg, poudre pour solution injectable	SE/H/1494/001	34009 300 634 3 9	LABORATOIRE CHAUVIN	FR
ICECA 50 mg, poudre pour solution injectable	SE/H/1494/001	34009 550 229 7 8	LABORATOIRE CHAUVIN	FR
ICECA 50 mg, poudre pour solution injectable	SE/H/1494/001	34009 550 229 8 5	LABORATOIRE CHAUVIN	FR