15 December 2022
EMA/794434/2022
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): cefuroxime axetil

Procedure No. PSUSA/00009099/202204

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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
Зинат 250 mg филмирани таблетки	IE/H/0716/004	20020074	GLAXOSMITHKLINE TRADING SERVICES LIMITED	BG
Zinnat 125 mg granule pro perorální suspenzi	IE/H/0716/001	15/390/92-A/C	GLAXOSMITHKLINE (IRELAND) LIMITED	CZ
Cefuroxim-ratiopharm® 500 mg Filmtabletten	DE/H/1426/002	70941.00.00	RATIOPHARM GMBH	DE
Cefuroxim-ratiopharm® 250 mg Filmtabletten	DE/H/1426/001	70940.00.00	RATIOPHARM GMBH	DE
Elobact-Trockensaft 125 mg/5 ml, Granulat zur Herstellung einer Suspension zum Einnehmen	IE/H/0716/001	16468.00.01	HEXAL AG	DE
Zinnat, 250 mg õhukese polümeerikattega tabletid	IE/H/0716/004	226498	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Zinnat, 500 mg õhukese polümeerikattega tabletid	IE/H/0716/005	226598	GLAXOSMITHKLINE (IRELAND) LIMITED	EE
Zinnat 250 mg granulado para suspensión oral	ES/H/0236/002	59.063	GLAXOSMITHKLINE S.A.	ES
ZINNAT 125 mg/5 ml ENFANTS ET NOURRISSONS, granulés pour suspension buvable en flacon	IE/H/0716/001	NL16772	LABORATOIRE GLAXOSMITHKLINE	FR
CEFUROXIME BIOGARAN 500 mg, comprimé pelliculé	not available	NL21711	LABORATOIRES SAINT-GERMAIN	FR
CEFUROXIME ZENTIVA 250 mg, comprimé pelliculé	not available	NL14426	LABORATOIRES PAUCOURT	FR
ZINNAT 125 mg,	IE/H/0716/003	NL14830	LABORATOIRE	FR

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comprimé pelliculé			GLAXOSMITHKLINE	
ZINNAT 250 mg, comprimé pelliculé	IE/H/0716/004	NL14425	LABORATOIRE GLAXOSMITHKLINE	FR
Zinadol 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	IE/H/0716/005	1965003	GLAXOSMITHKLINE SINGLE MEMBER A.E.B.E.	GR
Zinnat 125 mg/5 ml granule za oralnu suspenziju	not available	HR-H-715978020	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HR
ZINNAT 500 mg filmom obložene tablete	not available	HR-H-565616124	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HR
Zinnat 250 mg filmom obložene tablete	not available	HR-H-074775680	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HR
ZINNAT 125 mg filmom obložene tablete	not available	HR-H-391373111	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HR
Zinnat 125 mg/5 ml granulátum belsoleges szuszpenzióhoz	IE/H/0716/001	OGYI-T-1830/01	GLAXOSMITHKLINE TRADING SERVICES LIMITED	HU
Zinnat 250 mg/5 ml granules for oral suspension.	IE/H/0716/002	PA 1077/15/1	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Zinnat 250 mg film-coated tablets	IE/H/0716/004	PA 1077/15/3	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Zinnat 125 mg/5 ml granulato per sospensione orale	IE/H/0716/001	026915049	GLAXOSMITHKLINE S.P.A.	IT
CEFUROXIMA EG 500 mg compresse rivestite con film	IT/H/0370/002	026917031	EG S.P.A.	IT
CEFUROXIMA EG 500 mg compresse rivestite con film	IT/H/0370/002	026917106	EG S.P.A.	IT
CEFUROXIMA EG 250 mg compresse rivestite con film	IT/H/0370/001	026917029	EG S.P.A.	IT

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TILEXIM 500 mg Compresse rivestite con film	not available	027020039	I.B.N. SAVIO S.R.L.	IT
TILEXIM 500 mg Compresse rivestite con film	not available	027020054	I.B.N. SAVIO S.R.L.	IT
TILEXIM 250 mg Compresse rivestite con film	not available	027020027	I.B.N. SAVIO S.R.L.	IT
Oraxim 250 mg compresse rivestite con film	IT/H/0369/001	027002029	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Oraxim 500 mg compresse rivestite con film	IT/H/0369/002	027002106	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Oraxim 250 mg/5 ml granulato per sospensione orale	IT/H/0369/005	027002070	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Oraxim 125 mg/5 ml granulato per sospensione orale	IT/H/0369/004	027002043	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Oraxim 500 mg compresse rivestite con film	IT/H/0369/002	027002031	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
Oraxim 250 mg granulato per sospensione orale	IT/H/0369/003	027002056	MALESCI ISTITUTO FARMACOBIOLOGICO - S.P.A.	IT
ZINNAT 250 mg/5 ml Granulato per sospensione orale	IE/H/0716/002	026915076	GLAXOSMITHKLINE S.P.A.	IT
Zinnat 250 mg granulato per sospensione orale	ES/H/0236/002	026915052	GLAXOSMITHKLINE S.P.A.	IT
Zinnat 500 mg compresse rivestite con film	IE/H/0716/005	026915102	GLAXOSMITHKLINE S.P.A.	IT
ZINNAT 250 mg Compresse rivestite con film	IE/H/0716/004	026915025	GLAXOSMITHKLINE S.P.A.	IT

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Zinnat 125 mg/5 ml granulės geriamajai suspensijai	IE/H/0716/001	LT/1/94/0478/008	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Zinnat 125 mg/5 ml granules geriamajai suspensijai	IE/H/0716/001	LT/1/94/0478/009	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Zinnat 125 mg/5 ml granulės geriamajai suspensijai	IE/H/0716/001	LT/1/94/0478/007	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Zinnat 250 mg plėvele dengtos tabletės	IE/H/0716/004	LT/1/94/0478/003	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Zinnat 250 mg plėvele dengtos tabletės	IE/H/0716/004	LT/1/94/0478/004	GLAXOSMITHKLINE TRADING SERVICES LIMITED	LT
Zinnat 125 mg/5 ml granules for oral suspension	IE/H/0716/001	MA685/04103	SANDOZ PHARMACEUTICALS D.D.	MT
Zinnat 125 mg/5 ml granulaat voor orale suspensie	IE/H/0716/001	RVG 14376	SANDOZ B.V.	NL
Zinnat, 250 mg/5 ml, granulat do sporzadzania zawiesiny doustnej	IE/H/0716/002	4688	GLAXOSMITHKLINE (IRELAND) LIMITED	PL
Zipos 500 mg comprimidos revestidos por película	not available	4683983	INSTITUTO LUSO-FÁRMACO, LDA	PT
Zipos 250 mg/5 ml granulado para suspensão oral	not available	4691085	INSTITUTO LUSO-FÁRMACO, LDA	PT
Zipos 250 mg/5 ml granulado para suspensão oral	not available	3322484	INSTITUTO LUSO-FÁRMACO, LDA	PT
Zoref 250 mg/5 ml granulado para suspensão oral	IE/H/0716/002	4684189	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Zipos 125 mg/5 ml granulado para	not available	4690988	INSTITUTO LUSO-FÁRMACO, LDA	PT

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suspensão oral				
Zipos 125 mg/5 ml granulado para suspensão oral	not available	8796904	INSTITUTO LUSO-FÁRMACO, LDA	PT
Zoref 500 mg comprimidos revestidos por película	IE/H/0716/005	4684684	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Zinnat 125 mg/5 ml granule pentru suspensie orala	IE/H/0716/001	5184/2012/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zinnat 125 mg, comprimate filmate	IE/H/0716/003	2016/2009/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zinnat 250 mg, comprimate filmate	IE/H/0716/004	2017/2009/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zinnat 500 mg, comprimate filmate	IE/H/0716/005	2018/2009/01	GLAXOSMITHKLINE (IRELAND) LIMITED	RO
Zinnat 125 mg/5 ml zrnca za peroralno suspenzijo	IE/H/0716/001	H/92/01704/003	SANDOZ PHARMACEUTICALS D.D.	SI
Zinnat 125 mg/5 ml granulát na perorálnu suspenziu	IE/H/0716/001	15/0390/92-C/S	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SK
Zinnat 250 mg/5 ml granulát na perorálnu suspenziu	IE/H/0716/002	15/0246/13-S	GLAXOSMITHKLINE TRADING SERVICES LIMITED	SK
Zinnat 125mg/5ml granules for oral suspension	IE/H/0716/001	PL 48870/0042	SANDOZ PHARMACEUTICALS D.D.	XI
Zinnat 125 mg film-coated tablets	IE/H/0716/003	PL 48870/0043	SANDOZ PHARMACEUTICALS D.D.	XI