



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 June 2016
EMA/382258/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ceftazidime

Procedure no.: PSUSA/00000608/201510



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
Ceftazidim Kabi	PT/H/0186/003	H/10/00357/003 H/10/00357/004	Fresenius Kabi Deutschland Gmbh	Slovenia
Ceftazidim Stragen	DK/H/0925/004 DK/H/0925/005 DK/H/0925/006	38965 38966 38967	Stragen Nordic A/S	Denmark
Ceftazidime Fresenius Kabi	PT/H/0186/001	08-0387	Fresenius Kabi Polska Sp. Z O.O.	Latvia
Ceftazidime Fresenius Kabi	PT/H/0186/001	610808	Fresenius Kabi Polska Sp. Z O.O.	Estonia
Ceftazidime Fresenius Kabi	PT/H/0186/003	08-0389	Fresenius Kabi Polska Sp. Z O.O.	Latvia
Ceftazidime Fresenius Kabi	PT/H/0186/003	610708	Fresenius Kabi Polska Sp. Z O.O.	Estonia
Ceftazidime Stragen Uk	DK/H/0925/004 DK/H/0925/005 DK/H/0925/006	PL 21844/0006 PL 21844/0007 PL 21844/0008	Stragen Uk Ltd.	United Kingdom
Fortam	IE/H/0249/001 UK/H/4985/004	56.613 63.670	Glaxosmithkline S.A.	Spain
Fortam	UK/H/4985/003	56.612	Glaxosmithkline S.A.	Spain
Fortum	UK/H/4985/002	1-18138	Glaxosmithkline Pharma Gmbh.	Austria
Fortum	UK/H/4985/03/MR	1-18139	Glaxosmithkline Pharma Gmbh.	Austria
Fortum	UK/H/4985/04/MR	1-18140	Glaxosmithkline Pharma Gmbh.	Austria
Fortum	UK/H/4985/003	19519	Glaxo Group Limited	Cyprus
Fortum	UK/H/4985/02/MR	15/207/85-A/C	Glaxo Group Limited	Czech Republic
Fortum	UK/H/4985/03/MR UK/H/4985/04/MR	15/207/85-B/C 15/207/85-C/C	Glaxo Group Limited	Czech Republic
Fortum	UK/H/4985/02/MR UK/H/4985/03/MR UK/H/4985/04/MR	11447 11448 11449	Glaxosmithkline Pharma A/S	Denmark
Fortum	IE/H/0249/001	214898	Glaxo Group Limited	Estonia

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Fortum	IE/H/0249/01/MR (SOLUTION FOR INJ/INF 1G) UK/H/4985/004	NL13649-1 NL17978	Laboratoire Glaxosmithkline	France
Fortum	DE/H/3529/001	4374.00.00	Ratiopharm Gmbh	Germany
Fortum	DE/H/3529/002	4374.01.00	Ratiopharm Gmbh	Germany
Fortum	DE/H/3529/003	4374.02.00	Ratiopharm Gmbh	Germany
Fortum	IE/H/0249/01/MR UK/H/4985/04/MR	OGYI-T-1265/02 OGYI-T-1265/03	Glaxosmithkline Kft.	Hungary
Fortum	IE/H/0249/01/MR UK/H/4985/04/MR	843303 843304	Glaxosmithkline Ehf.	Iceland
Fortum	IE/H/0249/01/MR UK/H/4985/04/MR	PA 1077/7/2 PA 1077/7/3	Glaxosmithkline (Ireland) Limited	Ireland
Fortum	UK/H/4985/02/MR	PA 1077/7/1	Glaxosmithkline (Ireland) Limited	Ireland
Fortum	IT/H/361/04/MR LT/H/0109/01/MR	LT/1/94/0727/005 \$LT/1/94/0727/006	Glaxosmithkline Lietuva Uab	Lithuania
Fortum	UK/H/4985/04/MR	LT/1/94/0727/007 LT/1/94/0727/008	Glaxosmithkline Lietuva Uab	Lithuania
Fortum	UK/H/4985/003	MA 169/00101	Glaxo Operations	Malta
Fortum	UK/H/4985/02/MR UK/H/4985/03/MR	RVG 10540 RVG 12847	Glaxosmithkline B.V.	Netherlands
Fortum	UK/H/4985/04/MR	RVG 12848	Glaxosmithkline B.V.	Netherlands
Fortum	IE/H/0249/01/MR UK/H/4985/02/MR	11-8525 7140	Glaxosmithkline As	Norway
Fortum	UK/H/4985/04/MR	11-8526	Glaxosmithkline As	Norway
Fortum	IE/H/0249/001 UK/H/4985/004	R/0695 R/0696	Glaxosmithkline Export Ltd	Poland
Fortum	UK/H/4985/01/MR UK/H/4985/02/MR	R/0693 R/0694	Glaxosmithkline Export Ltd	Poland
Fortum	UK/H/4985/003	267/2007/01	Glaxo Wellcome Ltd	Romania
Fortum	UK/H/4985/003	267/2007/02	Glaxo Wellcome Uk Limited	Romania
Fortum	UK/H/4985/003	267/2007/03	Glaxo Wellcome Ltd	Romania

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Fortum	IE/H/0249/01/MR	15/0013/13-S	Glaxosmithkline Slovakia S.R.O.	Slovakia
Fortum	UK/H/4985/02/MR	15/0208/85-CS	Glaxosmithkline Slovakia S.R.O.	Slovakia
Fortum	UK/H/4985/04/MR	15/0014/13-S	Glaxosmithkline Slovakia S.R.O.	Slovakia
Fortum	IE/H/0249/01/MR	H/93/00650/001	Glaxosmithkline D.O.O.	Slovenia
Fortum	IE/H/0249/01/MR	48223	Glaxosmithkline Ab	Sweden
Fortum	IE/H/249/001	49654	Glaxosmithkline Ab	Sweden
Fortum	UK/H/4985/01/MR UK/H/4985/02/MR UK/H/4985/03/MR	48220 48221 49655	Glaxosmithkline Ab	Sweden
Fortum	UK/H/4985/04/MR	20655	Glaxosmithkline Ab	Sweden
Fortum	UK/H/4985/04/MR	48222	Glaxosmithkline Ab	Sweden
Fortum	UK/H/4985/001 UK/H/4985/02/MR UK/H/4985/03/MR	PL 00004/0292 PL 00004/0293 PL 00004/0304	Glaxo Operations Uk Ltd	United Kingdom
Fortum	UK/H/4985/04/MR	PL 00004/0294	Glaxo Operations Uk Ltd	United Kingdom
Fortum	UK/H/4985/04/MR	PL 00004/0424	Glaxo Operations Uk Ltd	United Kingdom
Fortum Enfants Et Nourrissons	UK/H/4985/001 UK/H/4985/002	NL13652-1 NL13653-1	Laboratoire Glaxosmithkline	France
Fortumset	IE/H/0249/01/MR (SOLUTION FOR INFUSION 1G)	NL21549	Laboratoire Glaxosmithkline	France
Fortumset	UK/H/4985/004	NL21548	Laboratoire Glaxosmithkline	France
Glazidim	IE/H/0249/001 UK/H/4985/004	BE127312 BE127321	Glaxosmithkline Pharmaceuticals Sa	Belgium
Glazidim	IE/H/0249/001 UK/H/4985/004	BE168113 BE168122	Glaxosmithkline Pharmaceuticals Sa	Belgium
Glazidim	UK/H/4985/002	BE127337	Glaxosmithkline Pharmaceuticals Sa	Belgium
Glazidim	UK/H/4985/003	30689	Glaxo Operations Uk Ltd	Finland
Glazidim	UK/H/4985/004	9245	Glaxosmithkline Oy	Finland
Glazidim	UK/H/4985/02/MR	9244	Glaxo Operations Uk Ltd	Finland

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Glazidim	UK/H/4985/04/MR	9245	Glaxosmithkline Oy	Finland
Glazidim	IE/H/0249/001 IT/H/0361/005 IT/H/0361/006 UK/H/4985/004	025212073 025212085 025212097 025212109	Glaxosmithkline S.P.A.	Italy
Glazidim	IE/H/0249/001 UK/H/4985/004	025212059 025212111 025212123	Glaxosmithkline S.P.A.	Italy
Glazidim	IT/H/0361/001 IT/H/0361/002 IT/H/0361/003 IT/H/0361/004	025212010 025212022 025212034 025212046	Glaxosmithkline S.P.A.	Italy
Glazidim	IE/H/0249/001 UK/H/4985/004	260/08 02 9693 260/08 02 9694	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Glazidim	IE/H/0249/001 UK/H/4985/004	260/08 02 9695 260/08 02 9696	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Glazidim	UK/H/4985/002	260/08 02 9692	Glaxosmithkline Pharmaceuticals Sa	Luxembourg
Kefadim		1637/05028682	Eurocept B.V.	Luxembourg
Kefadim		1637/05028683	Eurocept B.V.	Luxembourg
Kefadim		1637/05028684	Eurocept B.V.	Luxembourg
Kefadim		BE145792	Eurocept B.V.	Belgium
Kefadim		BE145801	Eurocept B.V.	Belgium
Solvetan	IE/H/0249/001	50076/3-11-10	Glaxosmithkline Aebe	Greece
Solvetan	UK/H/4985/004	74278/3-11-10	Glaxosmithkline Aebe	Greece
Spectrum		025222011 025222023 025222035	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Spectrum		025222047	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Spectrum		025222074 025222086 025222098 025222100	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy

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Spectrum		25222050	Sigma-Tau Industrie Farmaceutiche Riunite S.P.A.	Italy
Starcef		025859012 025859024 025859036	Fabbrica Italiana Ritrovati Medicinali Ed Affini F.I.R.M.A. - S.P.A.	Italy