



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/187078/2016187078/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: cefepime

Procedure no.: PSUSA/00000593/201506



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
Anticepim		22615/02-05-2012 \$ 56261/11/27-04-2012	Verisfield (Uk) Ltd	Greece
Axepim		3400937022866 \$ 3400937022927 \$ 3400937023009 \$ 3400937023177 \$ 3400937023238 \$ 3400937023467	Bristol-Myers Squibb	France
Bacteripime		II-18179	Tchaikapharma High Quality Medicines, Inc.	Bulgaria
Cefepim Fresenius Kabi	NL/H/1370/001 \$ NL/H/1370/002	BE376266 \$ BE376275	Fresenius Kabi Nv/Sa	Belgium
Cefepim Fresenius Kabi	NL/H/1370/001 \$ NL/H/1370/002	RVG 102543 \$ RVG 102544	Fresenius Kabi Nederland B.V.	Netherlands

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
Cefepim Hospira Benelux	PT/H/1016/001	BE449635	Hospira Benelux Bvba	Belgium
Cefepim Hospira Benelux	PT/H/1016/001 \$ PT/H/1016/002	BE 449635 \$ BE 449644 \$ BE449644	Hospira Benelux Bvba	Belgium
Cefepim Hospira Benelux	PT/H/1016/002	BE449644	Hospira Benelux Bvba	Belgium
Cefepim Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	5363-I-662/14 \$ 5363-I-663/14 \$ 5363-I-664/14 \$ 5363-I-665/14	Hospira Uk Ltd	Slovenia
Cefepim Hospira Uk	PT/H/1016/002	5363-I-666/14 \$ 5363-I-667/14	Hospira Uk Ltd	Slovenia

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Cefepim Kabi	NL/H/1370/001 \$ NL/H/1370/002	5363-I-850/11 \$ 5363-I-851/11	Fresenius Kabi Deutschland Gmbh	Slovenia
Cefepim Mip	NL/H/2986/001	BE468675-468684-470764-470773	Mip Pharma Gmbh	Belgium
Cefepim Mip	NL/H/2986/001 \$ NL/H/2986/002	135975 \$ 135976	Mip Pharma Gmbh	Austria
Cefepim Mip	NL/H/2986/001 \$ NL/H/2986/002	15/146/15-C \$ 15/147/15-C	Mip Pharma Gmbh	Czech Republic
Cefepim Mip	NL/H/2986/001 \$ NL/H/2986/002	49550 \$ 49551	Mip Pharma Gmbh	Sweden

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Cefepim Mip	NL/H/2986/001 \$ NL/H/2986/002	52730 \$ 52731	Mip Pharma Gmbh	Denmark
Cefepim Mip	NL/H/2986/001 \$ NL/H/2986/002	90357.00.00 \$ 90358.00.00	Mip Pharma Gmbh	Germany
Cefepim Mip	NL/H/2986/001 \$ NL/H/2986/002	BE468675 \$ BE468684	Mip Pharma Gmbh	Belgium
Cefepim Mip	NL/H/2986/001/DC \$ NL/H/2986/002/DC	13-9595 \$ 13-9596	Mip Pharma Gmbh	Norway
Cefepim Mip	NL/H/2986/001/DC \$ NL/H/2986/002/DC	OGYI-T-22772/01-03 \$ OGYI-T-22772/04-06	Mip Pharma Gmbh	Hungary

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Cefepim Mip Pharma	NL/H/2986/001 \$ NL/H/2986/002	31606 \$ 31607	Mip Pharma Gmbh	Finland
Cefepim Normon	PT/H/0812/001 \$ PT/H/0812/002	86681.00.00 \$ 86682.00.00	Laboratorios Normon, S.A.	Germany
Cefepim Rotexmedica	PT/H/0916/001 \$ PT/H/0916/002	87870.00.00 \$ 87871.00.00	Panmedica	Germany
Cefepim Sandoz	AT/H/0298/001	1-29785	Sandoz Gmbh	Austria
Cefepim Sandoz	AT/H/0298/002 \$ AT/H/0298/003	1-29786 \$ 1-29787	Sandoz Gmbh	Austria

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
Cefepima Accord Healthcare Limited	PT/H/449/01 \$ PT/H/449/02	5622352 \$ 5622360 \$ 5622402 \$ 5622410	Accord Healthcare Limited	Portugal
Cefepima Accord Healthcare S.L.U.	PT/H/449/01/DC \$ PT/H/449/02/DC	75147 \$ 75148	Accord Healthcare S.L.U.	Spain
Cefepima Hikma		5626213 \$ 5626221 \$ 5626239 \$ 5626254 \$ 5626262 \$ 5626270	Hikma Farmacêutica (Portugal), S.A.	Portugal
Cefepima Hospira	PT/H/1016/001	606518-1	Hospira Productos Farmacéuticos Y Hospitalarios, S.L.	Spain
Cefepima Hospira	PT/H/1016/002	60516-7	Hospira Productos Farmacéuticos Y Hospitalarios, S.L.	Spain

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Cefepima Hospira Italia Srl	PT/H/1016/001 \$ PT/H/1016/002	042477012 \$ 042477024 \$ 042477036 \$ 042477048 \$ 042477051 \$ 042477063	Hospira Italia Srl	Italy
Cefepima Hospira Portugal Lda	PT/H/1016/001 \$ PT/H/1016/002	5599410 \$ 5599428	Hospira Portugal Lda	Portugal
Cefepima Kabi	NL/H/1370/001	5316161 \$ 5316179 \$ 5316203 \$ 5345962 \$ 5345970 \$ 5346002	Fresenius Kabi Pharma Portugal Lda.	Portugal
Cefepima Kabi	NL/H/1370/001 \$ NL/H/1370/002	72750 \$ 72751	Fresenius Kabi España S.A.U.	Spain
Cefepima Norameda	PT/H/0800/001	5615430 \$ 5615448	Norameda Uab	Portugal

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
Cefepima Normon	78773	78772 \$ 78773	Laboratorios Normon, S.A.	Spain
Cefepima Normon	PT/H/812/01/DC \$ PT/H/812/02/DC	5583513 \$ 5583521 \$ 5583539 \$ 5583547	Laboratórios Normon, S.A.	Portugal
Cefepima Panpharma	PT/H/0916/001	5610431 \$ 5610449	Panmedica	Portugal
Cefepime Hospira	PT/H/1016/002	837414	Hospira Uk Ltd	Estonia
Cefepime Hospira Uk	PT/H/1016/001	837514	Hospira Uk Ltd	Estonia

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Cefepime Hospira Uk	PT/H/1016/001	OGYI-T-22627/01 \$ OGYI-T-22627/03	Hospira Uk Ltd	Hungary
Cefepime Hospira Uk	PT/H/1016/001	OGYI-T-22627/02	Hospira Uk Ltd	Hungary
Cefepime Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	14-0120 \$ 14-0121	Hospira Uk Ltd	Latvia
Cefepime Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	15/0186/14-S \$ 15/0187/14-S	Hospira Uk Ltd	Slovakia
Cefepime Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	20140108 \$ 20140109	Hospira Uk Ltd	Bulgaria

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Cefepime Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	22007 \$ 22008	Hospira Uk Ltd	Poland
Cefepime Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	6408/2014/01-03 \$ 6409/2014/01-03	Hospira Uk Ltd	Romania
Cefepime Hospira Uk	PT/H/1016/001 \$ PT/H/1016/002	LT/1/14/3559/001 \$ LT/1/14/3559/002 \$ LT/1/14/3559/003 \$ LT/1/14/3559/004 \$ LT/1/14/3559/005 \$ LT/1/14/3559/006	Hospira Uk Ltd	Lithuania
Cefepime Hospira Uk	PT/H/1016/002	OGYI-T-22627/04 \$ OGYI-T-22627/05	Hospira Uk Ltd	Hungary
Cefepime Hospira Uk	PT/H/1016/002	OGYI-T-22627/06	Hospira Uk Ltd	Hungary

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
Cefepime Kabi		UP/I-530-09/12-01/693 \$ UP/I-530-09/12-01/694	Fresenius Kabi D.O.O.	Croatia
Cefepime Kabi	NL/H/1370/001	3197/2011/01 \$ 3197/2011/02 \$ 3197/2011/03 \$ 3197/2011/04 \$ 3197/2011/05 \$ 3197/2011/06	Fresenius Kabi Romania S.R.L.	Romania
Cefepime Kabi	NL/H/1370/001 \$ NL/H/1370/002	18483 \$ 18484	Fresenius Kabi Polska Sp. Z O.O.	Poland
Cefepime Kabi	NL/H/1370/001 \$ NL/H/1370/002	21099 \$ 21100	Fresenius Kabi Hellas A.E.	Cyprus
Cefepime Kabi	NL/H/1370/001 \$ NL/H/1370/002	2115/14-1-2011 \$ 2116/14-1-2011	Fresenius Kabi Hellas A.E.	Greece

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Cefepime Mip	NL/H/2986/001 \$ NL/H/2986/002	15-0047 \$ 15-0048	Mip Pharma Gmbh	Latvia
Cefepime Mip	NL/H/2986/001 \$ NL/H/2986/002	861514 \$ 861614	Mip Pharma Gmbh	Estonia
Cefepime Mip	NL/H/2986/001 \$ NL/H/2986/002	RVG 113862 \$ RVG 113863	Mip Pharma Gmbh	Netherlands
Cefepime Mip	NL/H/2986/001/DC \$ NL/H/2986/002/DC	LT/1/14/3666/001-003 \$ LT/1/14/3666/004-006	Mip Pharma Gmbh	Lithuania
Cefepime Mylan		NL 35 529	Mylan S.A.S	France

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Cefepime Mylan		NL 35 530	Mylan S.A.S	France
Cefepime Norameda	PT/H/0800/001	13-0100	Norameda Uab	Latvia
Cefepime Norameda	PT/H/0800/001	30349	Norameda Uab	Finland
Cefepime Norameda	PT/H/0800/001	803612	Norameda Uab	Estonia
Cefepime Norameda	PT/H/0800/001	LT/1/13/3180/001 \$ LT/1/13/3180/002	Norameda Uab	Lithuania

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
Cefepime Panpharma		34009 494 754 1 4 \$ 34009 494 755 8 2 \$ 34009 494 756 4 3 \$ 34009 494 757 0 4 \$ 34009 494 758 7 2 \$ 34009 578 466 7 1 \$ 34009 578 467 3 2	Panmedica	France
Cefepime Panpharma		34009 494 759 3 3 \$ 34009 494 760 1 5 \$ 34009 494 761 8 3 \$ 34009 494 762 4 4 \$ 34009 494 763 0 5 \$ 34009 578 469 6 1 \$ 34009 578 470 4 3	Panmedica	France
Cefepime Panpharma	PT/H/0916/001	21698	Panmedica	Poland
Cefepime Panpharma	PT/H/0916/001	21698 \$ 21699	Panmedica	Poland
Cefepime Sandoz	AT/H/0298/001 \$ AT/H/0298/002 \$ AT/H/0298/003	BE380527 \$ BE380536 \$ BE380545	Sandoz N.V.	Belgium

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Cefepimă Mip	NL/H/2986/001 \$ NL/H/2986/002	7422/2015/01-02-03 \$ 7423/2015/01-02-03	Mip Pharma Gmbh	Romania
Cepim		028896013 \$ 028896025 \$ 028896037	Polifarma S.P.A	Italy
Cepimex		028900013 \$ 028900025	Bruno Farmaceutici	Italy
Critipeme	AT/H/0298/002 \$ AT/H/0298/003	17829 \$ 17830	Sandoz Gmbh	Poland
Critipime	AT/H/0298/002	20110011	Sandoz Pharmaceuticals D.D.	Bulgaria

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Deltacef		21568 \$ 21569 \$ 21570	Medochemie Ltd.	Cyprus
Gencef		1362 \$ 2664	Genepharm S.A.	Greece
Maxinject		93818/29-12-2014	Cooper S.A. Pharmaceuticals	Greece
Maxipime		028899019 \$ 028899021 \$ 028899033	Bristol-Myers Squibb S.R.L.	Italy
Maxipime		1-20597	Bristol-Myers Squibb Gesmbh	Austria

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Maxipime		1-20599	Bristol-Myers Squibb Gesmbh	Austria
Maxipime		15/0139/97-S	Bristol-Myers Squibb Spol. S R.O.	Slovakia
Maxipime		152296 \$ 152396	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Estonia
Maxipime		2006028413/0200757 \$ 2006028414/0200761	Bristol-Myers Squibb Belgium S.A.	Luxembourg
Maxipime		2275584	Bristol-Myers Squibb Farmacêutica Portuguesa, Sa	Portugal

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Maxipime		44320.00.00 \$ 44321.00.00	Bristol-Myers Squibb Gmbh & Co. Kgaa	Germany
Maxipime		BE 165733	Bristol-Myers Squibb Belgium Nv	Belgium
Maxipime		BE 165733	Bristol-Myers Squibb Belgium S.A.	Belgium
Maxipime		LT/1/97/1728/001	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Lithuania
Maxipime		OGYI-T- 6111/01	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Hungary

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Maxipime		OGYI-T- 6111/02	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Hungary
Verapime		38067/10 \$ 38069/10	Demo Abee	Greece
Zefipime		16292 \$ 39689/13	Vocate φαρμακευτική αε	Greece
алфацеф		20140246 \$ 20140247	Medochemie Ltd.	Bulgaria
максипим		9900171	Bristol-Myers Squibb Gyogyszerkereskedelmi Kft.	Bulgaria

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цефепим Мip	NL/H/2986/001 \$ NL/H/2986/002	20150076 \$ 20150077	Mip Pharma Gmbh	Bulgaria
цефепим каби	NL/H/1370/001	20120366	Fresenius Kabi Bulgaria Eood	Bulgaria
цефепим панфарма	PT/H/0916/001	20130209 \$ 20130210	Panpharma	Bulgaria
Maxipime		7461-7462-7463	Bristol-Myers Squib Polska	Poland
Cefepima PANLUETOL		78811--78810	Ibermedgen	Spain

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Maxipime 1g		50062	Vianex S.A.	Greece
Maxipime 2g		50063	Vianex S.A.	Greece
Maxipime 500mg		50078	Vianex S.A.	Greece