



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/185266/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: pamidronate

Procedure no.: PSUSA/00002269/201505



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
Aredia		1-20736 \$ 1-22393	Novartis Pharma Gmbh (Art57)	Austria
Aredia		33081.00.00 \$ 33081.01.00 \$ 33081.02.00 \$ 33081.03.00	Novartis Pharma Gmbh (Art57)	Germany
Aredia		5291/2005/01	Novartis Pharma Gmbh (Art57)	Romania
Aredia		5363-I-784/09 \$ 5363-I-785/09	Novartis Pharma Gmbh (Art57)	Slovenia
Aredia		62129 \$ 62130 \$ 62132	Novartis Farmacéutica S.A. (Art57)	Spain
Aredia		BE150473 \$ BE199044	Novartis Pharma N.V. (Art57)	Belgium
Aredia		PL 00101/0479 \$ PL 00101/0518 \$ PL 00101/0519 \$ PL 00101/0521	Novartis Pharmaceuticals Uk Limited (Art57)	United Kingdom
Disodium Pamidronate	UK-H-2961-001-MR	PL 00289/0854	Teva Uk Limited Brampton Road, Hampden Park	United Kingdom
Disodium Pamidronate Medac	FI/H/0263/001	PL 11587/0027	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	United Kingdom
Disodium Pamidronate Wockhardt Uk	UK/H/0681/001 \$ UK/H/0681/002 \$ UK/H/0681/003 \$ UK/H/0681/004	PA 1339/7/1 \$ PA 1339/7/2 \$ PA 1339/7/3 \$ PA 1339/7/4	Wockhardt Uk Ltd	Ireland
Disodium Pamidronate Wockhardt Uk	UK/H/0681/001 \$ UK/H/0681/002 \$ UK/H/0681/003 \$ UK/H/0681/004	PL 29831/0071 \$ PL 29831/0072 \$ PL 29831/0073 \$ PL 29831/0074	Wockhardt Uk Ltd	United Kingdom

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
Ostepam	NL 27768	3400936159204 \$ 3400936159372 \$ 3400936159662 \$ 3400936159723 \$ 3400936159891 \$ 3400936181892 \$ 3400936687677 \$ 3400936879546 \$ 3400936879607 \$ 3400936880146 \$ 3400936880207 \$ 3400936880375	Nordic Pharma	France
Pamidran Hospira	SE/H/0420/001 \$ SE/H/0420/002	3967486 \$ 3967585 \$ 3967684\$ 3967683	Hospira Portugal Lda	Portugal
Pamidrin	UK-H-2961-001-MR	2005100070	Teva Pharma Belgium N.V.	Luxembourg
Pamidrin	UK-H-2961-001-MR	BE279492 \$ BE279501 \$ BE279517 \$ BE279526	Teva Pharma Belgium N.V.	Belgium
Pamidro-Cell	FI/H/0264/001	59201.00.00	Cell Pharm Gmbh	Germany
Pamidrocell	FI/H/0264/001	38651	Stada Arzneimittel Ag	Denmark
Pamidron Hexal	DK/H/0498/001	58750.00.00	Hexal Ag	Germany
Pamidronaatdina trium Pch	UK-H-2961-001-MR	RVG 32237	Pharmachemie B.V.	Netherlands
Pamidronat Dinatrium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	1-25977 \$ 1-25978 \$ 1-25979	Hospira Deutschland Gmbh	Austria
Pamidronat Hexal	DK/H/0498/001	32203	Hexal Ag	Denmark
Pamidronat Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	53548.00.00 \$ 53548.01.00 \$ 53548.02.00	Hospira Deutschland Gmbh	Germany

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
Pamidronat Medac	FI/H/0263/001	12236	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Poland
Pamidronat Teva	UK-H-2961-001-MR	22193	Teva Sweden Ab	Sweden
Pamidronat Torrex		7602/2015/01 \$ 7602/2015/02 \$ 7602/2015/03 \$ 7602/2015/04 \$ 7602/2015/05 \$ 7602/2015/06 \$ 7602/2015/07 \$ 7602/2015/08 \$	Chiesi Pharmaceuticals Gmbh	Romania
Pamidronat Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	BE 237587 \$ BE 237596 \$ BE 237605 \$ BE 237614	Hospira Benelux Bvba	Belgium
Pamidronat-Gry	UK-H-2961-001-MR	62532.00.00	Teva Gmbh	Germany
Pamidronaat	NL/H/0616/002 \$ NL/H/0616/003	RVG 30873 \$ RVG 30874	Hospira Benelux Bvba	Netherlands
Pamidronatdinatrium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	17959 \$ 17960 \$ 17961	Hospira Uk Ltd	Sweden
Pamidronatdinatrium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	33122 \$ 33123 \$ 33124	Hospira Uk Ltd	Denmark
Pamidronatdinatrium Hospira	SE/H/0420/001 \$ SE/H/0420/003	16969 \$ 16971	Hospira Uk Ltd	Finland
Pamidronaat	NL/H/0616/001	RVG 30872	Hospira Benelux Bvba	Netherlands
Pamidronatdinatrium Teva	UK-H-2961-001-MR	37718	Teva Denmark A/S	Denmark
Pamidronate De Sodium Hospira	SE/H/0420/001 \$ SE/H/0420/002	34009 381 696 6 9 \$ 34009 381 697 2 0 \$ 34009 381 698 9 8 \$ 34009 381 699 5 9 \$	Hospira France	France

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
Pamidronate De Sodium Mylan	FI/H/0263/001	NL 29884	Mylan S.A.S	France
Pamidronate De Sodium Ratiopharm	FR-H-0559-001	NL 31803	Ratiopharm Gmbh	France
Pamidronate Disodium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	26510/01-11-2013	Hospira Uk Ltd	Greece
Pamidronate Disodium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	LT/1/05/0230/001 \$ LT/1/05/0230/002 \$ LT/1/05/0230/003 \$ LT/1/05/0230/004 \$ LT/1/05/0230/005 \$ LT/1/05/0230/006 \$ LT/1/05/0230/007 \$ LT/1/05/0230/008	Hospira Uk Ltd	Lithuania
Pamidronate Disodium Hospira Uk		PL 04515/0118	Hospira Uk Ltd	United Kingdom
Pamidronate Disodium Hospira Uk		PL 04515/0120 \$ PL 04515/0121	Hospira Uk Ltd	United Kingdom
Pamidronate		19499	Pharmaceutical Trading Co Ltd	Cyprus
Pamidronate Disodium Tillomed Laboratories		PL 11311/0217 \$ PL 1311/0218 \$ PL 1311/0219 \$ PL 1311/0220	Tillomed Laboratories Ltd	United Kingdom
Pamidronate Eg	FI/H/0264/001	BE265273 \$ BE265282 \$ BE265291 \$ BE265307	Eurogenerics Sa	Belgium

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
Pamidronate Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	OGYI-T-10313/01 \$ OGYI-T-10313/02 \$ OGYI-T-10313/03 \$ OGYI-T-10313/04	Hospira Uk Ltd	Hungary
Pamidronate Medac	FI/H/0263/001	44/079/06-C	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Czech Republic
Pamidronato Bioindustria L.I.M.	National	036868014 \$ 036868026 \$ 036868038 \$ 036868040	Bioindustria Lim Laboratorio Italiano Medicinali Spa	Italy
Pamidronato Disodico Hikma	National	035744010 \$ 035744022 \$ 035744034 \$ 035744046	Hikma Italia S.P.A.	Italy
Pamidronato Disodico Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	035581014/M \$ 035581026/M \$ 035581038/M \$ 035581040/M	Hospira Italia Srl	Italy
Pamidronato Hikma		5052576 \$ 5052600 \$ 5052618	Hikma Farmacêutica (Portugal), S.A.	Portugal
Pamidronato Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	64.945 \$ 64.946 \$ 64.947	Hospira Uk Ltd	Spain
Pamidronato Teva	UK-H-2961-001-MR	037127014 \$ 037127026/M \$ 037127038/M \$ 037127040/M \$ 037127053/M \$ 037127065/M \$ 037127077/M \$ 037127089/M \$ 037127091/M \$ 037127103/M \$ 037127115/M \$ 037127127/M	Teva Italia S.R.L.	Italy

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
Pamidronic Acid Hospira		AA734/00901	Hospira Uk Ltd	Malta
Pamidronatdinatrium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	01-11119 \$ 01-11120 \$ 01-11121	Hospira Uk Ltd	Norway
Pamidronic Acid Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	1907/09110025 \$ 1907/09110026 \$ 1907/09110027	Hospira Benelux Bvba	Luxembourg
amidronatdinatrium Hospira	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	IS/1/05/008/01 \$ IS/1/05/008/02 \$ IS/1/05/008/03	Hospira Uk Ltd	Iceland
Pamifos	FI/H/0263/001	17565	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Finland
Pamifos	FI/H/0263/001	20330	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Sweden
Pamifos	FI/H/0263/001	36053	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Denmark
Pamifos	FI/H/0263/001	44/0199/06-S	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Slovakia
Pamifos	FI/H/0263/001	59200.00.00	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Germany
Pamifos	FI/H/0263/001	OGYI-T-20184/01 \$ OGYI-T-20184/02 \$ OGYI-T-20184/03 \$ OGYI-T-20184/04	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Hungary
Pamifos 90 90 Mg		PL9380	Viphaarm S.A.	Poland
Pamifos-30		9378	Viphaarm S.A.	Poland
Pamifos-60		9379	Viphaarm S.A.	Poland
Paminject	FI/H/0264/001	18178	Stada Arzneimittel Ag	Finland

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
Pamipro	FI/H/0263/001	RVG 30331	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Netherlands
Pamired		7654/2015/01	Dr. Reddy's Laboratories Romania Srl	Romania
Pamired	177/2007/01	7653/2015/01	Dr. Reddy's Laboratories Romania Srl	Romania
Pamisol	SE/H/0420/001 \$ SE/H/0420/002 \$ SE/H/0420/003	11690 \$ 11691 \$ 11692	Hospira Uk Ltd	Poland
Pamitor		03-0328	Chiesi Pharmaceuticals Gmbh	Latvia
Pamitor		LT/1/03/3352/001-004	Chiesi Pharmaceuticals Gmbh	Lithuania
Pamitor		1-24706	Chiesi Pharmaceuticals Gmbh	Austria
Pamitor		10126	Chiesi Pharmaceuticals Gmbh	Poland
Pamitor		44/0147/05-S	Chiesi Pharmaceuticals Gmbh	Slovakia
Pamitor		451404	Chiesi Pharmaceuticals Gmbh	Estonia
Pamitor		H/04/01212/001\$ H/04/01212/002 \$H/04/01212/003	Chiesi Pharmaceuticals Gmbh	Slovenia
Pamitor		II-10991	Tchaikapharma High Quality Medicines, Inc.	Bulgaria
Pamitor		OGYI-T-8332/01 \$ OGYI-T-8332/02 \$ OGYI-T-8332/03 \$ OGYI-T-8332/04 \$ OGYI-T-8332/05 \$ OGYI-T-8332/06	Chiesi Pharmaceuticals Gmbh	Hungary
Pamitor		UP/I-530-09/10-02/339	Chiesi Pharmaceuticals Gmbh	Croatia
Ribodronat	IT/H/229/01/MR	61521.00.00	Hikma Farmacêutica (Portugal), S.A.	Germany
Texpami	National	036645012 \$ 036645024 \$ 036645036 \$ 036645048	Pharmatex Italia Srl	Italy

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
axidronat 3 mg/ml Konzentrat zur Herstellung einer Infusionslösung	DE/H/3032/001	72734.00.00	axios Pharma GmbH	Germany
Pamidronato Azevedos 15 mg Po para perfusao		5662499 5662598	Laboratorios Azevedos Industria Farmaceutica, S.A.	Portugal
Pamidronato Azevedos 30 mg Po para perfusao		"5662697 5662796	Laboratorios Azevedos Industria Farmaceutica, S.A.	Portugal
Pamidronato Azevedos 60 mg Po para perfusao		5662895 5662994	Laboratorios Azevedos Industria Farmaceutica, S.A.	Portugal
Pamidronato Azevedos 90 mg Po para perfusao		5663091 5663190	Laboratorios Azevedos Industria Farmaceutica, S.A.	Portugal
Pamidronate Disodium		S00610	Pharmaceutical Trading Co Ltd	Cyprus
Pamidronate Hospira		26510/01-11-2013	Hospira Uk Ltd	Greece
Dinatriumpamidronat Mylan	DE/H/3390/001/DC	85572.00.00 ENR 2185572	Mylan Dura GmbH	Germany
Pamidromyl	DE/H/3390/001/DC	28061 MTnr. 49639	Agila Specialties UK Limited (UK)	Denmark
Pamidromyl	DE/H/3390/001/DC	30233	Agila Specialties UK Limited (UK)	Finland
Pamidronate Disodium Agila	DE/H/3390/001/DC	21924	Mylan S.A.S.	Poland

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
Pamidronate disodium	DE/H/3390/001/DC	PL 04569/1548	Generics [UK] Ltd. t/a Mylan (UK)	United Kingdom
Disodium Pamidronate	N/A	AA 154/06101	Wockhardt Uk Ltd	Malta
Disodium pamidronate	N/A	S01024	Wockhardt Uk Ltd	Cyprus