



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 October 2015
EMA/270645/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: cilostazol

Procedure no.: PSUSA/00010209/201502



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
Boiser	EE/H/0193/002	042770038 042770040 042770065 042770077 042770091	Crinos S.P.A.	Italy
Boiser	EE/H/0193/002	042770115	Crinos S.P.A.	Italy
Cilostad	EE/H/0194/001	844514	Stada Arzneimittel Ag	Estonia
Cilostad	EE/H/0194/002	844414	Stada Arzneimittel Ag	Estonia
Cilostazol	MT-H-0159-001-DC	PL 00289/1850	Teva Uk Limited	United Kingdom
Cilostazol	MT-H-0159-001-DC	PL 00289/1850	Teva Uk Limited	United Kingdom
Cilostazol Adamed	EE/H/0189/001-002/DC	4633/22-1-2015	Adamed	Greece
Cilostazol Adamed	EE/H/0189/001-002/DC	4634/22-1-2015	Adamed	Greece
Cilostazol Binomil		78175	J. Uriach & Cía., S.A.	Spain

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
Cilostazol Cinfa		78222	Laboratorios Cinfa, S.A.	Spain
Cilostazol Elpen	DE/H/3921/001/DC	49734	Elpen Pharmaceutical Co. Inc.	Sweden
Cilostazol Elpen	DE/H/3921/001/DC	OGYI-T-22731/01-3	Elpen Pharmaceutical Co. Inc.	Hungary
Cilostazol Eql Pharma		48343	Eql Pharma Ab	Sweden
Cilostazol Evolan	SE/H/1516/001	50217	Evolan Pharma Ab	Sweden
Cilostazol Evolan	SE/H/1516/002	50218	Evolan Pharma Ab	Sweden
Cilostazol Galenica	MT/H/0167/001	45336/13/17-9-2014	Galenica Sa	Greece
Cilostazol Hexal	MT/H/0161/001	88746.00.00	Hexal Ag	Germany
Cilostazol Kern Pharma		78148	Kern Pharma, S.L.	Spain

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
Cilostazol Labormed	MT/H/0163/001/DC	MA711/00801	Labormed Pharma S.A.	Malta
Cilostazol Mylan	EE/H/0189	78988	Mylan Pharmaceuticals S.L.	Spain
Cilostazol Mylan	EE/H/0189	79001	Mylan Pharmaceuticals S.L.	Spain
Cilostazol Normon		78146	Laboratorios Normon, S.A.	Spain
Cilostazol Pensa		78.177	Pensa Pharma, S.A	Spain
Cilostazol Pharmagenus		78227	Pharmagenus, S.A.	Spain
Cilostazol Ranbaxy	UK/H/5681/001	78244	Laboratorios Ranbaxy S.L.	Spain
Cilostazol Ranbaxy (Uk)	UK/H/5681/001	PL 14894/0722	Ranbaxy (Uk) Limited	United Kingdom
Cilostazol Ratiopharm		78179	Ratiopharm España, S.A.	Spain

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Cilostazol Sandoz	MT/H/0161/001	20130399	Sandoz Pharmaceuticals D.D.	Bulgaria
Cilostazol Sandoz	MT/H/0161/001	5982/2013/01-10	S.C. Sandoz S.R.L.	Romania
Cilostazol Sandoz	MT/H/0161/001	78224	Sandoz Farmacéutica, S.A.	Spain
Cilostazol Stada	EE/H/0193/002	78.694	Laboratorio Stada, S.L.	Spain
Cilostazol Stada	EE/H/0193/002	844614	Stada Arzneimittel Ag	Estonia
Cilostazol Stada	EE/H/0193/002	89799.00.00	Stadapharm Gmbh	Germany
Cilostazol Stada	EE/H/0194/001	16/0230/14-S	Stada Arzneimittel Ag	Slovakia
Cilostazol Stada	EE/H/0194/002	16/0231/14-S	Stada Arzneimittel Ag	Slovakia
Cilostazol Stada	EE/H/0194/002	83/153/14-C	Stada Arzneimittel Ag	Czech Republic
Cilostazol Stada Genéricos		78.181	Stada Genéricos, S.L.	Spain

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Cilostazol Teva	MT-H-0159-001-DC	6192/2014/01-12	Teva Pharmaceuticals S.R.L.	Romania
Cilostazol Teva	MT-H-0159-001-DC	78254	Teva Pharma S.L.U.; C/A Segura, 11, Edificio Albatros B, 1a Planta, Alcobendas, 28108, Madrid, Spain	Spain
Cilostazol Ucb Pharma		92986.00.00	Ucb Pharma Gmbh (Monheim De)	Germany
Cilostazol Ucb Pharma		92987.00.00	Ucb Pharma Gmbh (Monheim De)	Germany
Cilostazol-Elpen	DE/H/3921/001/DC	90515.00.00	Elpen Pharmaceutical Co. Inc.	Germany
Cilostazol-Teva	MT-H-0159-001-DC	OGYI-T-22564/01 OGYI-T-22564/02 OGYI-T-22564/03 OGYI-T-22564/04	Teva Gyógyszergyár Zrt	Hungary
Cilostazolo Sandoz	MT/H/0161/001	042365015 042365027 042365039 042365041 042365054 042365066 042365078 042365080 042365092 042365104	Sandoz S.P.A.	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
Cilozek	EE/H/0189/001	16/0170/14-S	Adamed	Slovakia
Cilozek	EE/H/0189/001	OGYI-T-22653/01 OGYI-T-22653/02 OGYI-T-22653/03 OGYI-T-22653/04	Adamed	Hungary
Cilozek	EE/H/0189/001-002/DC	840014	Adamed	Estonia
Cilozek	EE/H/0189/001-002/DC	840114	Adamed	Estonia
Cilozek	EE/H/0189/001/DC	21739	Adamed	Poland
Cilozek	EE/H/0189/002	16/0171/14-S	Adamed	Slovakia
Cilozek	EE/H/0189/002	OGYI-T-22653/05 OGYI-T-22653/06 OGYI-T-22653/07 OGYI-T-22653/08	Adamed	Hungary
Cilozek	EE/H/0189/002/DC	21740	Adamed	Poland
Claudiasil	MT/H/0168/01/DC	45540/13/13-06-2014	Libytec Pharmaceutical S.A.	Greece

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
Claudienne	EE/H/0189/001	83/175/14-C	Adamed	Czech Republic
Claudienne	EE/H/0189/002	83/176/14-C	Adamed	Czech Republic
Decilosal	MT/H/0161/001	21544	Sandoz Gmbh	Poland
Dilsatan	MT/H/0161/001	828913	Sandoz Pharmaceuticals D.D.	Estonia
Dilsatan	MT/H/0161/001	LT/1/13/3380/001 LT/1/13/3380/002 LT/1/13/3380/003 LT/1/13/3380/004 LT/1/13/3380/005 LT/1/13/3380/006 LT/1/13/3380/007 LT/1/13/3380/008 LT/1/13/3380/009 LT/1/13/3380/010	Sandoz Pharmaceuticals D.D.	Lithuania
Dilsatan	MT/H/0161/001	LT/1/13/3380/001 LT/1/13/3380/002 LT/1/13/3380/003 LT/1/13/3380/004 LT/1/13/3380/005 LT/1/13/3380/006 LT/1/13/3380/007 LT/1/13/3380/008 LT/1/13/3380/009	Sandoz Pharmaceuticals D.D.	Lithuania

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		LT/1/13/3380/010		
Dilsatan Sandoz Pharmaceuticals D.D.	MT/H/0161/001	13-0225	Sandoz Pharmaceuticals D.D.	Latvia
Dilsatan Sandoz Pharmaceuticals D.D.	MT/H/0161/001	13-0225	Sandoz Pharmaceuticals D.D.	Latvia
Dilvas®	MT/H/0163/001/DC	5961/2013/01	Labormed Pharma S.A.	Romania
Ekistol		70.125	Lacer S.A.	Spain
Ekistol		70.126	Lacer S.A.	Spain
Noclaud	NULL	6455/2014/01-02	Egis Pharmaceuticals Plc	Romania
Noclaud	NULL	6456/2014/01-02	Egis Pharmaceuticals Plc	Romania
Noclaud	NULL	83/148/14-C	Egis Pharmaceuticals Plc	Czech Republic

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Noclaud	NULL	83/149/14-C	Egis Pharmaceuticals Plc	Czech Republic
Pladizol	UK/H/5366/001/DC	6134/2014/01	Glenmark Pharmaceuticals S.R.O.	Romania
Pladizol	UK/H/5366/001/DC	83/205/14-C	Glenmark Pharmaceuticals S.R.O.	Czech Republic
Pletal	UK/H/0292/001	034887354/M	Otsuka Pharmaceutical Europe Ltd	Italy
Pletal	UK/H/0292/001	034887354/M	Otsuka Pharmaceutical Europe Ltd	Italy
Pletal	UK/H/0292/001	25896	Otsuka Pharmaceutical Europe Ltd	Sweden
Pletal	UK/H/0292/001	25896	Otsuka Pharmaceutical Europe Ltd	Sweden
Pletal	UK/H/0292/001	66599.01.00	Otsuka Pharmaceutical Europe Ltd	Germany
Pletal	UK/H/0292/001	66599.01.00	Otsuka Pharmaceutical Europe Ltd	Germany

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Pletal	UK/H/0292/001	69562	Otsuka Pharmaceutical Europe Ltd	Spain
Pletal	UK/H/0292/001	69562	Otsuka Pharmaceutical Europe Ltd	Spain
Pletal	UK/H/0292/001	NL 34755	Otsuka Pharmaceutical Europe Ltd	France
Pletal	UK/H/0292/001	NL 34755	Otsuka Pharmaceutical Europe Ltd	France
Pletal	UK/H/0292/001	PL 11515/0001	Otsuka Pharmaceutical Europe Ltd	United Kingdom
Pletal	UK/H/0292/001	PL 11515/0001	Otsuka Pharmaceutical Europe Ltd	United Kingdom
Pletal	UK/H/0292/002	034887240/M	Otsuka Pharmaceutical Europe Ltd	Italy
Pletal	UK/H/0292/002	034887240/M	Otsuka Pharmaceutical Europe Ltd	Italy
Pletal	UK/H/0292/002	25895	Otsuka Pharmaceutical Europe Ltd	Sweden
Pletal	UK/H/0292/002	25895	Otsuka Pharmaceutical Europe Ltd	Sweden
Pletal	UK/H/0292/002	66599.00.00	Otsuka Pharmaceutical Europe Ltd.	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
Pletal	UK/H/0292/002	66599.00.00	Otsuka Pharmaceutical Europe Ltd.	Germany
Pletal	UK/H/0292/002	69563	Otsuka Pharmaceutical Europe Ltd	Spain
Pletal	UK/H/0292/002	69563	Otsuka Pharmaceutical Europe Ltd	Spain
Pletal	UK/H/0292/002	NL 34754	Otsuka Pharmaceutical Europe Ltd	France
Pletal	UK/H/0292/002	PL 11515/0002	Otsuka Pharmaceutical Europe Ltd	United Kingdom
Pletal	UK/H/0292/002	PL 11515/0002	Otsuka Pharmaceutical Europe Ltd	United Kingdom
Sollazon	NULL	14-0014	Egis Pharmaceuticals Plc	Latvia
Sollazon	NULL	14-0015	Egis Pharmaceuticals Plc	Latvia
Velyn	EE/H/0189/001/DC	6275/2014/01-10	Terapia S.A	Romania
Velyn	EE/H/0189/002/DC	6276/2014/01-10	Terapia S.A	Romania

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селексол	EE/H/0194/001	20140144	Stada Arzneimittel Ag	Bulgaria
селексол	EE/H/0194/002	20140145	Stada Arzneimittel Ag	Bulgaria
Cilostazol		78178	Zentiva, K.S.	Spain
Cilostazol Galenica	MT/H/0167/001	MA978/00201	Galenica Sa	Malta
Cilostazol Galenica	MT/H/0167/001	II-25144/19.03.2014	Galenica Sa	Bulgaria
Cilostazol Galenica	MT/H/0167/001	6598/2014/01	Galenica Sa	Romania
Cilostazol Apotex	SE/H/1516/001	83/426/14-C	Apotex Europe B.V.	Czech Republic
Cilostazol Apotex	SE/H/1516/002	83/427/14-C	Apotex Europe B.V.	Czech Republic
Cilos	EE/H/0196/001-002/DC	4256/21-1-2015	Winmedica Pharmaceutical LTD	Greece

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Cilos	EE/H/0196/001-002/DC	4255/21-1-2015	Winmedica Pharmaceutical LTD	Greece
Cilostazol Win Medica	EE/H/0196/001/DC	848814	Win Medica Ltd	Estonia
Cilostazol Win Medica	EE/H/0196/002/DC	848714	Win Medica Ltd	Estonia
Cilostop		21780	Biofarm Sp. Z O.O.	Poland
Cilostazol Hspt	MT/H/159-162/01/DC	OGYI-T-22582/01	Hosptess Kft.	Hungary