



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/676059/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: pimecrolimus

Procedure no.: PSUSA/00002411/201603



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
Aregen	DK/H/0340/001	33504	Meda As	Denmark
Elidel		9641	Meda Pharma Gmbh & Co. Kg	Poland
Elidel		HR-H-820593463	Medical Intertrade D.O.O.	Croatia
Elidel	DK/H/0039/001	46/0335/03-S	Meda Pharma Spol. S R.O.	Slovakia
Elidel	DK/H/0039/001	H/03/00536/001 \$ H/03/00536/002 H/03/00536/003 \$ H/03/00536/004 H/03/00536/005	Meda Pharma Gmbh & Co. Kg	Slovenia
Elidel	DK/H/0039/001	LT/1/07/0930/001	Meda Pharma Sia	Lithuania
Elidel	DK/H/0339/001	0135/08019622	Meda Pharma Gmbh & Co. Kg	Luxembourg
Elidel	DK/H/0339/001	02-1563	Meda As	Norway
Elidel	DK/H/0339/001	02-0184	Meda Pharma Sia	Latvia
Elidel	DK/H/0339/001	036006017 \$ 036006029 \$ 036006031 \$ 036006043	Meda Pharma S.P.A.	Italy
Elidel	DK/H/0339/001	1-24689	Meda Pharma Gmbh	Austria
Elidel	DK/H/0339/001	19087	Meda Ab	Sweden
Elidel	DK/H/0339/001	19427	Meda Pharmaceuticals S.A.	Cyprus
Elidel	DK/H/0339/001	32700	Meda As	Denmark
Elidel	DK/H/0339/001	42425/19-06-2015	Meda Pharmaceuticals S.A.	Greece
Elidel	DK/H/0339/001	428603	Meda Pharma Sia	Estonia
Elidel 10 mg/g krém	DK/H/0339/001	46/156/02-C	Meda Pharma S.R.O.	Czech Republic
Elidel	DK/H/0339/001	54804.00.00	Meda Pharma Gmbh & Co. Kg	Germany
Elidel	DK/H/0339/001	6063/2014/01 \$ 6063/2014/02 \$ 6063/2014/03 \$ 6063/2014/04 \$ 6063/2014/05	Meda Pharma Gmbh & Co. Kg	Romania
Elidel	DK/H/0339/001	65029	Meda Pharma S.A.U.	Spain
Elidel	DK/H/0339/001	BE240712	S.A. Meda Pharma N.V.	Belgium
Elidel	DK/H/0339/001	IS/1/02/030/01	Meda Ab	Iceland
Elidel	DK/H/0339/001	MA806/01201	Meda Pharmaceuticals Ltd	Malta
Elidel	DK/H/0339/001	RVG 28742	Meda Pharma B.V.	Netherlands
Elidel	DK/H/0339/001 \$ DK/H/0339/001/MR	4145280 \$ 4145389 \$ 4145488 \$ 4145587	Meda Pharma – Produtos Farmacêuticos, S.A.	Portugal

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Elidel	DK/H/0339/001 \$ UK/H/0339/001	OGYI-T-9011/01 \$ OGYI-T-9011/02 \$ OGYI-T-9011/03	Meda Pharma Hungary Kft.	Hungary
Elidel	UK/H/0339/001	17364	Meda Oy	Finland
елидел Elidel	DK/H/0339/001/MR	20030658	Meda Pharma Gmbh & Co. Kg	Bulgaria
Elidel	UK/H/0339/001	PL 15142/0250	Meda Pharmaceuticals Ltd.	United Kingdom