



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 May 2016
EMA/447143/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substances: azelastine / fluticasone

Procedure No.: PSUSA/00010067/201510



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
Azecort	DE/H/3356/001	021884	Meda Pharmaceuticals S.A.	Cyprus
Azecort	DE/H/3356/001	49786	Meda As	Denmark
Azecort	DE/H/3356/001	IS/1/13/023/01	Meda Ab	Iceland
Azecort	DE/H/3356/001	MA 806/01701	Meda Pharmaceuticals Ltd	Malta
Azecort	DE/H/3356/001	PA1332/046/001	Meda Health Sales Ireland Limited	Ireland
Azecort	DE/H/3356/001/DC	21401	Meda Pharma Gmbh & Co. Kg	Poland
Azecort	DE/H/3356/01/DC	5596614 & 5596622	Meda Pharma – Produtos Farmacêuticos, S.A.	Portugal
Azecort Nosová	DE/H/3356/001/DC	24/0056/13-S	Meda Pharma Spol. S R.O.	Slovakia
Azelastine / Fluticasone	DE/H/3356/001	PL 15142/0259	Meda Pharmaceuticals Ltd	United Kingdom
Bileni	DE/H/3356/001	13-0043	Meda Pharma Sia	Latvia
Bileni	DE/H/3356/001	808413	Meda Pharma Sia	Estonia
Bileni	DE/H/3356/001/DC	LT/1/13/3225/001 & LT/1/13/3225/002 & LT/1/13/3225/003 & LT/1/13/3225/004	Meda Pharma Sia	Lithuania
Bileni	DE/H/3356/001/DC	OGYI-T-22424/01	Meda Pharma Hungary Kft.	Hungary
Bileni	DE/H/3356/001/DC	OGYI-T-22424/02 & OGYI-T-22424/03 & OGYI-T-22424/04	Meda Pharma Hungary Kft.	Hungary
Dygaro	DE/H/3356/001	041809017 & 041809029 & 041809031 & 041809043	Meda Pharma S.P.A.	Italy
Dymista	DE/H/3355/001	021885	Meda Pharmaceuticals S.A.	Cyprus
Dymista	DE/H/3355/001	041808015 & 041808027 & 041808039 & 041808041	Meda Pharma S.P.A.	Italy
Dymista	DE/H/3355/001	1-31812	Meda Pharma Gmbh	Austria
Dymista	DE/H/3355/001	11-8686	Meda As	Norway
Dymista	DE/H/3355/001	13-0044	Meda Pharma Sia	Latvia
Dymista	DE/H/3355/001	2013080274	Meda Pharma Gmbh & Co. Kg	Luxembourg
Dymista	DE/H/3355/001	30255	Meda Oy	Finland
Dymista	DE/H/3355/001	31742/10-06-2014	Meda Pharmaceuticals S.A.	Greece

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Dymista	DE/H/3355/001	34009 275 630 5 8 & 34009 275 631 1 9	Meda Pharma Sas	France
Dymista	DE/H/3355/001	49785	Meda As	Denmark
Dymista	DE/H/3355/001	76618	Meda Pharma S.A.U.	Spain
Dymista	DE/H/3355/001	808513	Meda Pharma Sia	Estonia
Dymista	DE/H/3355/001	85237.00.00	Meda Pharma Gmbh & Co. Kg	Germany
Dymista	DE/H/3355/001	H/13/00519/001 & H/13/00519/002 & H/13/00519/003 & H/13/00519/004	Meda Pharma Gmbh & Co. Kg	Slovenia
Dymista	DE/H/3355/001	IS/1/13/025/01	Meda Ab	Iceland
Dymista	DE/H/3355/001	MA 806/01601	Meda Pharmaceuticals Ltd	Malta
Dymista	DE/H/3355/001	PL 15142/0258	Meda Pharmaceuticals Ltd	United Kingdom
Dymista	DE/H/3355/001/DC	21388	Meda Pharma Gmbh & Co. Kg	Poland
Dymista	DE/H/3355/001/DC	LT/1/13/3227/001 & LT/1/13/3227/002 & LT/1/13/3227/003 & LT/1/13/3227/004	Meda Pharma Sia	Lithuania
Dymista	DE/H/3355/001/DC	OGYI-T-22423/01 & OGYI-T-22423/04	Meda Pharma Hungary Kft.	Hungary
Dymista	DE/H/3355/001/DC	OGYI-T-22423/03	Meda Pharma Hungary Kft.	Hungary
Dymista	DE/H/3355/01	47084	Meda Ab	Sweden
Dymista	DE/H/3355/01/DC	5596630 & 5596648	Meda Pharma – Produtos Farmacêuticos, S.A.	Portugal
Dymista	DE/H/3356/001	PA1332/045/001	Meda Health Sales Ireland Limited	Ireland
Dymista	DE/H/3910/001	RVG 114215	Meda Pharma B.V.	Netherlands
Dymista Nosová	DE/H/3355/001/DC	24/0055/13-S	Meda Pharma Spol. S R.O.	Slovakia
Dymista Sprej Za Nos		UP/I-530-09/12-01/139	Medical Intertrade D.O.O.	Croatia
Dymistalan	DE/H/3356/001	69/ 339/13-C	Meda Pharma S.R.O.	Czech Republic
Dymistalin	DE/H/3910/001	90467.00.00	Meda Pharma Gmbh & Co. Kg	Germany
Dymistin	DE/H/3355/001	69/338/13-C	Meda Pharma S.R.O.	Czech Republic
Dymistin	DE/H/3911/001	90468.00.00	Meda Pharma Gmbh & Co. Kg	Germany
Dymistin	DE/H/3911/001	RVG 114221	Meda Pharma B.V.	Netherlands

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Dyvistalin	DE/H/3356/001	47085	Meda Ab	Sweden
Dyvistanil	DE/H/3356/001	2013080276	Meda Pharma Gmbh & Co. Kg	Luxembourg
Dyvistanil	DE/H/3356/001	85238.00.00	Meda Pharma Gmbh & Co. Kg	Germany
Synaze	DE/H/3356/001	1-31923	Meda Pharma Gmbh	Austria
Synaze	DE/H/3356/001	11-8687	Meda As	Norway
Synaze	DE/H/3356/001	30256	Meda Oy	Finland
Synaze	DE/H/3356/001	34009 275 632 8 7 & 34009 275 633 4 8	Meda Pharma Sas	France
Synaze	DE/H/3356/001	5572/2013/01 & 5572/2013/02 & 5572/2013/03 & 5572/2013/04	Meda Pharma Gmbh & Co. Kg	Romania
Synaze	DE/H/3356/001	76619	Meda Pharma S.A.U.	Spain
Synaze	DE/H/3356/001	H/13/01478/001 & H/13/01478/002 & H/13/01478/003 & H/13/01478/004	Meda Pharma Gmbh & Co. Kg	Slovenia
Synaze Sprej Za Nos		UP/I-530-09/12-01/141	Medical Intertrade D.O.O.	Croatia
азекорт Azecort	DE/H/3356/001/DC	20130144	Meda Pharma Gmbh & Co. Kg	Bulgaria
димиста Dymista	DE/H/3355/001/DC	20130142	Meda Pharma Gmbh & Co. Kg	Bulgaria