



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/622830/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: azelastine

Procedure no.: PSUSA/00000277/201412



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
Afluon		33527/22-9-2009	Meda Pharmaceuticals S.A.	GR
Afluon		59.791	Meda Pharma Gmbh & Co. Kg	ES
Afluon		64557/15-09-2011	Meda Pharmaceuticals S.A.	GR
Afluon		S00794	Meda Pharmaceuticals S.A.	CY
Afluon Sucralosa	UK/H/0256/004	79061	Meda Pharma S.A.U.	ES
Afluón	UK/H/0256/001,2	62.373	Meda Pharma S.A.U.	ES
Alerdual		347 673.7	Meda Pharma Sas	FR
Allergodil		1-19732	Meda Pharma Gmbh	AT
Allergodil		1-19772	Meda Pharma Gmbh	AT
Allergodil		10626	Meda Pharma Gmbh & Co. Kg	PL
Allergodil		14752	Meda As	DK
Allergodil		15768.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil		182097	Meda Pharma Sia	EE
Allergodil		2011/071189	S.A. Meda Pharma N.V.	LU
Allergodil		2011/071190	S.A. Meda Pharma N.V.	LU
Allergodil		2159184	Meda Pharma Gmbh & Co. Kg	PT
Allergodil		22667.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil		234598	Meda Pharma Sia	EE
Allergodil		24/002/97-C	Meda Pharma Gmbh & Co. Kg	CZ
Allergodil		24/0205/97-S	Meda Pharma Gmbh & Co. Kg	SK
Allergodil		24/0206/97-S	Meda Pharma Gmbh & Co. Kg	SK
Allergodil		34009 347 671 4	Meda Pharma Sas	FR
Allergodil		34009338 305-95	Meda Pharma Sas	FR
Allergodil		5151782	Meda Pharma Gmbh & Co. Kg	PT
Allergodil		5363-I-2537/10	Meda Pharma Gmbh & Co. Kg	SI
Allergodil		5416/2004/02	Meda Pharma Gmbh & Co. Kg	RO
Allergodil		64/0157/99-S	Meda Pharma Gmbh & Co. Kg	SK
Allergodil		64/210/00-C	Meda Pharma Gmbh & Co. Kg	CZ
Allergodil		7602	Meda Pharma Gmbh & Co. Kg	PL
Allergodil		96-0663	Meda Pharma Sia	LV
Allergodil		98-0067	Meda Pharma Sia	LV
Allergodil		BE159433	S.A. Meda Pharma N.V.	BE
Allergodil		BE198536	Meda Pharma N.V.	BE
Allergodil		OGYI-T-4877/01	Meda Pharma Gmbh	HU

Allergodil		OGYI-T-4877/02	Meda Pharma Hungary Kft.	HU
Allergodil		UP/I-530-09/10-01/516	Medical Intertrade D.O.O.	HR
Allergodil	UK/H/0256/001	028310035/M	Meda Pharma S.P.A.	IT
Allergodil	UK/H/0256/001	028310047/M	Meda Pharma S.P.A.	IT
Allergodil	UK/H/0256/001	2801884	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Allergodil	UK/H/0256/001	2801983	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Allergodil	UK/H/0256/001	30205	Meda As	DK
Allergodil	UK/H/0256/001	4328381	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Allergodil	UK/H/0256/001	43763.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil	UK/H/0256/001	RVG 22946	Meda Pharma B.V.	NL
Allergodil	UK/H/0256/001/MR	1-22726	Meda Pharma Gmbh	AT
Allergodil	UK/H/0256/003	80970.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil	UK/H/0256/004	028310086	Meda Pharma S.P.A.	IT
Allergodil	UK/H/0256/004	028310098	Meda Pharma S.P.A.	IT
Allergodil	UK/H/0256/004	028310100	Meda Pharma S.P.A.	IT
Allergodil	UK/H/0256/004	RVG 112404	Meda Pharma B.V.	NL
Allergodil	UK/H/0256/004/DC	1-35726	Meda Pharma Gmbh	AT
Allergodil	UK/H/4326/001	43852	Meda Ab	SE
Allergodil	UK/H/4327/001	80972.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil Akut		15768.00.01	Meda Pharma Gmbh & Co. Kg	DE
Allergodil Akut	UK/H/0255/001	43765.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil Akut Duo		46278.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil Akut Duo		46280.00.00	Meda Pharma Gmbh & Co. Kg	DE
Allergodil Bid	UK/H/0256/003/DC	NJA	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Allergodil Forte	UK/H/4757/001/DC	51235	Meda As	DK
Allergodil Nasal	UK/H/0256/003/DC	46484	Meda As	DK
Allergodil Nevel		RVG 17886	Meda Pharma B.V.	NL
Allergodrop	UK/H/0255/001/MR	1-22725	Meda Pharma Gmbh	AT
Allergospray		1-24127	Meda Pharma Gmbh	AT
Allergospray	UK/H/0256/001/DC	1-31500	Meda Pharma Gmbh	AT
Allergospray Mit Sucralose	UK/H/0256/003	1-31499	Meda Pharma Gmbh	AT
Allespray		039848015	Meda Pharma S.P.A.	IT

Astepro	UK/H/0256/003	PA1332/039/001	Meda Health Sales Ireland Limited	IE
Astepro	UK/H/0256/003/DC	28429	Meda Oy	FI
Astepro	UK/H/4757/001	042362018	Meda Pharma S.P.A.	IT
Astepro	UK/H/4757/001	042362020	Meda Pharma S.P.A.	IT
Astepro	UK/H/4757/001	042362032	Meda Pharma S.P.A.	IT
Astepro	UK/H/4757/001	48346	Meda Ab	SE
Astepro	UK/H/4757/001	79105	Meda Pharma S.A.U.	ES
Astepro	UK/H/4757/001	88285.00.00	Meda Pharma Gmbh & Co. Kg	DE
Astepro	UK/H/4757/001	PA1332/39/2	Meda Health Sales Ireland Limited	IE
Astepro	UK/H/4757/001	PL 15142/0236	Meda Pharmaceuticals Ltd	GB
Astepro	UK/H/4757/001	RVG 112403	Meda Pharma B.V.	NL
Astepro	UK/H/4757/001/DC	135728	Meda Pharma Gmbh	AT
Astepro	UK/H/4757/001/DC	51236	Meda As	DK
Astepro Forte	UK/H/4757/001/DC	30962	Meda Oy	FI
Azela-Vision Md Sine	SE/H/1183/01/DC	135328	Omnivision Gmbh	AT
Azela-Vision Md Sine	SE/H/1183/01/DC	87678.00.00	Omnivision Gmbh	DE
Azela-Vision Sine	DE/H/3852/001/DC FORMERLY SE/H/1105/001/DC	1-31702	Omnivision Gmbh	AT
Azela-Vision Sine	DE/H/3852/001/DC FORMERLY SE/H/1105/001/DC	84112.00.00	Omnivision Gmbh	DE
Azelastin Meda Pharma	UK/H/4329/001,2	80974.00.00	Meda Pharma Gmbh & Co. Kg	DE
Azelastin-POS	AT/H/0351/001	1-30138	URSAPHARM GmbH	AT
Azelastin-POS	AT/H/0351/002	1-35924	URSAPHARM GmbH	AT
Azelastin-COMOD	AT/H/0454/001	1-31587	URSAPHARM GmbH	AT
Azelastin-POS	AT/H/0351/002	BE393391	URSAPHARM Benelux B.V.	BE
Azelastin-COMOD	AT/H/0454/001	BE428452	URSAPHARM Benelux B.V.	BE
Azelastin-POS	AT/H/0351/001	64/300/11-CZ	URSAPHARM GmbH	CZ
Azelastin-COMOD	AT/H/0454/001	64/057/13-C	URSAPHARM GmbH	CZ
Azelastin-POS	AT/H/0351/001	80315.00.00	URSAPHARM Arzneimittel GmbH	DE
Azelastin-COMOD	AT/H/0454/001	87738.00.00	URSAPHARM Arzneimittel GmbH	DE
Azelastin-POS	AT/H/0351/002	89370.00.00	URSAPHARM Arzneimittel GmbH	DE
Azelastin-POS	AT/H/0351/001	201230014	URSAPHARM Benelux B.V.	LU

Azelastin-COMOD	AT/H/0454/001	2012120184	URSAPHARM Benelux B.V.	LU
Azelastin-POS	AT/H/0351/001	AA063/00701	URSAPHARM Arzneimittel GmbH	MT
Azelastin-POS	AT/H/0351/002	RVG 112977	URSAPHARM Benelux B.V.	NL
Azelastin-POS	AT/H/0351/001	RVG 106263	URSAPHARM Benelux B.V.	NL
Azelastin-COMOD	AT/H/0454/001	RVG 111896	URSAPHARM Benelux B.V.	NL
Azelastin-POS	AT/H/0351/001	18610	URSAPHARM Poland sp. z o.o.	PL
Azelastin-COMOD	AT/H/0454/001	20665	URSAPHARM Poland sp. z o.o.	PL
Azelastin-POS	AT/H/0351/002	2012/08116_REG	URSAPHARM Arzneimittel GmbH	SK
Azelastin-POS	AT/H/0351/001	64/0380/11-S	URSAPHARM Arzneimittel GmbH	SK
Azelastin-URSAPHARM	AT/H/0454/001	64/0452/12-S	URSAPHARM Arzneimittel GmbH	SK
Azelastine Meda Health	UK/H/0255/001	PA 1332/010/001	Meda Health Sales Ireland Limited	IE
Azelastine Omnivision	SE/H/1183/01/DC	47906	Omnivision GmbH	SE
Azelastinhydrochlorid Stadapharm	DE/H/3273/001	84681.00.00	Stadapharm GmbH	DE
Azep		2169084	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Azep		3765989	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Carelastin	UK/H/4326/001	80971.00.00	Meda Pharma GmbH & Co. Kg	DE
Corifina		61056	Meda Pharma S.A.U.	ES
Corifina	UK/H/0255/001	62.372	Meda Pharma S.A.U.	ES
Lasticom	UK/H/0255/001	027673045/M	Meda Pharma GmbH	IT
Lastin		02-1198	Meda As	NO
Lastin		12076	Meda Oy	FI
Lastin		13954	Meda Ab	SE
Lastin		940201(IS)	Meda Ab	IS
Lastin		99-3196	Meda As	NO
Lastin	UK/H/0256/001	14563	Meda Ab	SE
Lastin	UK/H/0256/001/MR	13658	Meda Oy	FI
Lastinaz	UK/H/0256/003	43854	Meda Ab	SE
Loxin	UK/H/256/002	43764.00.00	Dr. Gerhard Mann Chem.-	DE

			Pharm. Fabrik Gmbh	
Oculastin	UK/H/0255/001	14564	Meda Ab	SE
Oculastin	UK/H/0255/001	2802080	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Oculastin	UK/H/0255/001	2802189	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Oculastin	UK/H/0255/001	4240982	Meda Pharma – Produtos Farmacêuticos, S.A.	PT
Oculastin	UK/H/0255/001	RVG 22947	Meda Pharma B.V.	NL
Oculastin	UK/H/0255/001/MR	13659	Meda Oy	FI
Oculastin	UK/H/0255/001/MR	30206	Meda As	DK
Optilast	UK/H/0256/001	PA 1332/009/001	Meda Health Sales Ireland Limited	IE
Otrivin Neusallergie		RVG 26128	Novartis Consumer Health B.V.	NL
Proallergodil		345 506-6	Meda Pharma Sas	FR
Rhinolast		PA 1332/15/1	Meda Health Sales Ireland Limited	IE
Rhinolast	UK/H/0256/004	88284.00.00	Meda Pharma Gmbh & Co. Kg	DE
Rhinolast	UK/H/0256/004/DC	30959	Meda Oy	FI
Rhinolast	UK/H/4328/001	80973.00.00	Meda Pharma Gmbh & Co. Kg	DE
Rhinolast Hayfever		PA1322/015/002	Meda Health Sales Ireland Limited	IE
Rhinolast S	UK/H/0256/004	PL 15142/0235	Meda Pharmaceuticals Ltd	GB
Rhinolast S	UK/H/0256/004/DC	PA 1332/15/4	Meda Health Sales Ireland Limited	IE
Rhinolast S	UK/H/4327/001/DC	PA 1332/015/003	Meda Health Sales Ireland Limited	IE
Rinelaz	UK/H/0256/004	48345	Meda Ab	SE
Tebarat	ES/H/0178/001/DC	041957010	Laboratorios Salvat, S.A.	IT
Tebarat	ES/H/0178/001/DC	041957022	Laboratorios Salvat, S.A.	IT
Tebarat	ES/H/0178/001/DC	041957034	Laboratorios Salvat, S.A.	IT
Tebarat	ES/H/0178/001/DC	5596408	Laboratorios Salvat, S.A.	PT
Tebarat	ES/H/0178/001/DC	5596416	Laboratorios Salvat, S.A.	PT
Tebarat	ES/H/0178/001/DC	5596424	Laboratorios Salvat, S.A.	PT
Tebarat	ES/H/0178/001/DC	77005	Laboratorios Salvat, S.A.	ES
Vividrin Akut Azelastin Antiallergische	UK/H/255/002	43766.00.00	Dr. Gerhard Mann Chem.- Pharm. Fabrik Gmbh	DE

Vividrin® Akut		22668.00.00	Meda Pharma Gmbh & Co. Kg	DE
Vividrin® Akut		46279.00.00	Meda Pharma Gmbh & Co. Kg	DE
алергодил		9800144	Meda Pharma Gmbh & Co. Kg	BG
алергодил		9900378	Meda Pharma Gmbh & Co. Kg	BG