



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 June 2025

Case number: EMA/PSUR/0000248486

Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: azelastine / fluticasone

Procedure no.: PSUSA/00010067/202410

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Product full name (in authorisation country)	MRP/DCP or CP Authorisation number	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
Dymista 125 mikrogram + 50 mikrogram/sprayning nässpray, suspension	DE/H/3355/001	30255	VIATRIS OY	FI
Dymista 125 mikrogrammaa + 50 mikrogrammaa / annos nenäsumute, suspensio	DE/H/3355/001	30255	VIATRIS OY	FI
Dymista 137 mcg/50 mcg/dose Solution pour pulvérisation nasale	DE/H/3355/001	2013080274	VIATRIS HEALTHCARE GMBH	LU
Dymista 137 microgramas / 50 microgramas por aplicação Suspensão para pulverização nasal	DE/H/3355/001	5596648	VIATRIS HEALTHCARE LDA.	PT
Dymista 137 microgramas / 50 microgramas por aplicação Suspensão para pulverização nasal	DE/H/3355/001	5596630	VIATRIS HEALTHCARE LDA.	PT
Dymista 137 micrograme/50 micrograme/doză spray nazal suspensie	DE/H/3355/001	11003/2018/01	VIATRIS HEALTHCARE LIMITED	RO
Dymista 137 micrograme/50 micrograme/doză spray nazal suspensie	DE/H/3355/001	11003/2018/02	VIATRIS HEALTHCARE LIMITED	RO
Dymista 137 micrograme/50 micrograme/doză spray nazal suspensie	DE/H/3355/001	11003/2018/03	VIATRIS HEALTHCARE LIMITED	RO
Dymista 137 micrograme/50 micrograme/doză spray nazal suspensie	DE/H/3355/001	11003/2018/04	VIATRIS HEALTHCARE LIMITED	RO

DYMISTA 137 microgrammes/50 microgrammes, suspension pour pulvérisation nasale	DE/H/3355/001	34009 275 630 5 8	VIATRIS MEDICAL	FR
DYMISTA 137 microgrammes/50 microgrammes, suspension pour pulvérisation nasale	DE/H/3355/001	34009 275 631 1 9	VIATRIS MEDICAL	FR
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808027	VIATRIS HEALTHCARE LIMITED	IT
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808039	VIATRIS HEALTHCARE LIMITED	IT
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808041	VIATRIS HEALTHCARE LIMITED	IT
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808015	VIATRIS HEALTHCARE LIMITED	IT
Dymista 137 microgramos/50 microgramos /aplicación, suspensión para pulverización nasal	DE/H/3355/001	76618	VIATRIS HEALTHCARE LIMITED	ES
Dymista 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	DE/H/3355/001	PA23355/010/001	VIATRIS HEALTHCARE LIMITED	IE
Dymista 137 mikrograma/50 mikrograma po potisku, sprej za nos, suspenzija	not available	HR-H-228449282	VIATRIS HRVATSKA D.O.O.	HR
Dymista 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/003	VIATRIS HEALTHCARE LIMITED	LT

Dymista 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/002	VIATRIS HEALTHCARE LIMITED	LT
Dymista 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/001	VIATRIS HEALTHCARE LIMITED	LT
Dymista 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/004	VIATRIS HEALTHCARE LIMITED	LT
Dymista 137 mikrogrami/ 50 mikrogrami devā deguna aerosols, suspensija	DE/H/3355/001	13-0044	VIATRIS HEALTHCARE LIMITED	LV
Dymista 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3355/001	1-31812	VIATRIS HEALTHCARE LIMITED	AT
Dymista 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija	DE/H/3355/001	H/13/00519/001	MEDA PHARMA GMBH & CO. KG	SI
Dymista 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija	DE/H/3355/001	H/13/00519/002	MEDA PHARMA GMBH & CO. KG	SI
Dymista 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija	DE/H/3355/001	H/13/00519/003	MEDA PHARMA GMBH & CO. KG	SI
Dymista 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija	DE/H/3355/001	H/13/00519/004	MEDA PHARMA GMBH & CO. KG	SI
Dymista Control 137 micrograms / 50 micrograms per Actuation Nasal Spray	not available	PL 46302/0094	MYLAN PRODUCTS LIMITED	XI

Dymista Nasal Spray 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	DE/H/3355/001	MA1507/00701	VIATRIS HEALTHCARE LIMITED	MT
Dymista Nasal Spray 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	not available	PL 46302/0162	MYLAN PRODUCTS LIMITED	XI
Dymista Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3355/001	2013080274	VIATRIS HEALTHCARE GMBH	LU
Dymista Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3355/001	85237.00.00	VIATRIS HEALTHCARE GMBH	DE
Dymista nefúði 137 míkrógrömm / 50 míkrógrömm í hverjum úðaskammti Nefúði, dreifa	DE/H/3355/001	IS/1/13/025/01	VIATRIS APS	IS
Dymista Neusspray 137 microgram/50 microgram, neusspray, suspensie	DE/H/3910/001	RVG 114215	MYLAN HEALTHCARE B.V.	NL
Dymista nosová aerodisperzia 137 mikrogramov / 50 mikrogramov v jednom vstreknutí nosová suspenzná aerodisperzia	DE/H/3355/001	24/0055/13-S	VIATRIS HEALTHCARE LIMITED	SK
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befújásonként	DE/H/3355/001	OGYI-T-22423/02	VIATRIS HEALTHCARE LIMITED	HU
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befújásonként	DE/H/3355/001	OGYI-T-22423/03	VIATRIS HEALTHCARE LIMITED	HU
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befújásonként	DE/H/3355/001	OGYI-T-22423/04	VIATRIS HEALTHCARE LIMITED	HU

Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befújásonként	DE/H/3355/001	OGYI-T-22423/01	VIATRIS HEALTHCARE LIMITED	HU
Dymista Ρινικό Εκνέφωμα 137 μικρογραμμάρια / 50 μικρογραμμάρια ανά ψεκασμό Ρινικό Εκνέφωμα, Εναιώρημα	DE/H/3355/001	021885	VIATRIS HEALTHCARE LIMITED	CY
Dymista Ρινικό Εκνέφωμα 137 μικρογραμμάρια / 50 μικρογραμμάρια ανά ψεκασμό Ρινικό Εκνέφωμα, Εναιώρημα	DE/H/3355/001	84307/07-08-2018	VIATRIS HEALTHCARE LIMITED	GR
Dymista (137 mikrogramów + 50 mikrogramów)/dawkę donosową, aerazol do nosa, zawiesina	DE/H/3355/001	21388	VIATRIS HEALTHCARE LIMITED	PL
Dymista 137 mikrogram / 50 mikrogram per spray Nesespray, suspensjon	DE/H/3355/001	11-8686	VIATRIS AS	NO
Dymista, 137 mikrogrammi/50 mikrogrammi annuses ninasprei, suspensioon	DE/H/3355/001	808513	VIATRIS HEALTHCARE LIMITED	EE
Dymista, næsespray, suspension	DE/H/3355/001	49785	VIATRIS APS	DK
Dymistalin Nasenspray 137 Mikrogramm / 50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3910/001	90467.00.00	VIATRIS HEALTHCARE GMBH	DE