



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 June 2019
EMA/348238/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: azelastine / fluticasone

Procedure no.: PSUSA/00010067/201810

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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
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 137 microgramas / 50 microgramas por aplicação Suspensão para pulverização nasal	DE/H/3356/001	5596622	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Azecort 137 microgramas / 50 microgramas por aplicação Suspensão para pulverização nasal	DE/H/3356/001	5596614	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Azecort 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension	DE/H/3356/001	PA1332/046/001	MEDA HEALTH SALES IRELAND LIMITED	IE
Azecort Nasal Spray 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	DE/H/3356/001	MA 806/01701	MEDA PHARMACEUTICALS LIMITED	MT
Azecort nefúði 137 míkrogrömm / 50 míkrogrömm í hverjum úðaskammti Nefúði, dreifa	DE/H/3356/001	IS/1/13/023/01	MEDA AB	IS
Azecort nosová aerodisperzia 137 mikrogramov / 50 mikrogramov v jednom	DE/H/3356/001	24/0056/13-S	MYLAN IRE HEALTHCARE LIMITED	SK

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vstreknutí nosová suspenzná aerodisperzia				
Azecort, (137 mikrogramów + 50 mikrogramów)/dawkę donosową, aerozol do nosa, zawiesina	DE/H/3356/001	21401	MYLAN HEALTHCARE SP. Z.O.O.	PL
Azecort, næsespray, suspension	DE/H/3356/001	49786	MEDA AS	DK
Azelastine / Fluticasone Nasal Spray 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	DE/H/3356/001	PL 46302/0094	MYLAN PRODUCTS LIMITED	UK
Bileni 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3356/001	LT/1/13/3225/001	MEDA PHARMA SIA	LT
Bileni 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3356/001	LT/1/13/3225/002	MEDA PHARMA SIA	LT
Bileni 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3356/001	LT/1/13/3225/004	MEDA PHARMA SIA	LT
Bileni 137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3356/001	LT/1/13/3225/003	MEDA PHARMA SIA	LT

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
Bileni 137 mikrogrammi/ 50 mikrogrammi devā deguna aerosols, suspensija	DE/H/3356/001	13-0043	MEDA PHARMA SIA	LV
Bileni 137 mikrogrammi/50 mikrogrammi annuses ninasprei, suspensioon	DE/H/3356/001	808413	MEDA PHARMA SIA	EE
Bileni szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3356/001	OGYI-T-22424/02	MYLAN EPD KFT.	HU
Bileni szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3356/001	OGYI-T-22424/03	MYLAN EPD KFT.	HU
Bileni szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3356/001	OGYI-T-22424/04	MYLAN EPD KFT.	HU
Bileni szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3356/001	OGYI-T-22424/01	MYLAN EPD KFT.	HU
Bileni Πινικό Εκνέφωμα 137 μικρογραμμάρια / 50 μικρογραμμάρια ανά ψεκασμό Πινικό Εκνέφωμα, Εναιώρημα	DE/H/3356/001	021884	MEDA PHARMACEUTICALS S.A.	CY

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
Bileni Ρινικό Εκνέφωμα 137 μικρογραμμάρια / 50 μικρογραμμάρια ανά ψεκασμό Ρινικό Εκνέφωμα, Εναιώρημα	DE/H/3356/001	84308/07-08-2018	MEDA PHARMACEUTICALS S.A.	GR
DYGARO 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3356/001	041809017	MEDA PHARMA S.P.A.	IT
DYGARO 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3356/001	041809043	MEDA PHARMA S.P.A.	IT
DYGARO 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3356/001	041809031	MEDA PHARMA S.P.A.	IT
DYGARO 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3356/001	041809029	MEDA PHARMA S.P.A.	IT
Dymista 125 mikrogram + 50 mikrogram / dos nässpray, suspension	DE/H/3355/001	30255	MEDA OY	FI

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Dymista 125 mikrogram + 50 mikrogram/sprayning nässpray, suspension	DE/H/3355/01	47084	MEDA AB	SE
Dymista 125 mikrogrammaa + 50 mikrogrammaa / annos nenäsumute, suspensio	DE/H/3355/001	30255	MEDA OY	FI
Dymista 137 mcg/50 mcg/dose Solution pour pulvérisation nasale	DE/H/3355/001	2013080274	MEDA PHARMA GMBH & CO. KG	LU
Dymista 137 microgramas / 50 microgramas por aplicação Suspensão para pulverização nasal	DE/H/3355/001	5596648	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Dymista 137 microgramas / 50 microgramas por aplicação Suspensão para pulverização nasal	DE/H/3355/001	5596630	BGP PRODUCTS UNIPESOAAL, LDA.	PT
Dymista 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3355/001	11003/2018/01	MEDA PHARMA GMBH & CO. KG	RO
Dymista 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3355/001	11003/2018/02	MEDA PHARMA GMBH & CO. KG	RO
Dymista 137 micrograme/50 micrograme/doza spray	DE/H/3355/001	11003/2018/03	MEDA PHARMA GMBH & CO. KG	RO

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nazal, suspensie				
Dymista 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3355/001	11003/2018/04	MEDA PHARMA GMBH & CO. KG	RO
DYMISTA 137 microgrammes/50 microgrammes, suspension pour pulvérisation nasale	DE/H/3355/001	34009 275 630 5 8	MEDA PHARMA SAS	FR
DYMISTA 137 microgrammes/50 microgrammes, suspension pour pulvérisation nasale	DE/H/3355/001	34009 275 631 1 9	MEDA PHARMA SAS	FR
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808027	MEDA PHARMA S.P.A.	IT
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808039	MEDA PHARMA S.P.A.	IT

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Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808041	MEDA PHARMA S.P.A.	IT
Dymista 137 microgrammi/50 microgrammi per erogazione Spray nasale, sospensione	DE/H/3355/001	041808015	MEDA PHARMA S.P.A.	IT
Dymista 137 microgramos/50 microgramos /aplicación, suspensión para pulverización nasal	DE/H/3355/001	76618	MYLAN IRE HEALTHCARE LIMITED	ES
Dymista 137 mikrogram / 50 mikrogram per spray Nesespray, suspensjon	DE/H/3355/001	11-8686	MEDA AS	NO
Dymista 137 mikrogrami/ 50 mikrogrami devā deguna aerosols, suspensija	DE/H/3355/001	13-0044	MEDA PHARMA SIA	LV
Dymista 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3355/001	1-31812	MEDA PHARMA GMBH	AT

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Dymista 137 mikrogrammi/50 mikrogrammi annuses ninasprei, suspensioon	DE/H/3355/001	808513	MEDA PHARMA SIA	EE
Dymista 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija azelastinijev klorid/flutikazonpropionat	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 azelastinijev klorid/flutikazonpropionat	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 azelastinijev klorid/flutikazonpropionat	DE/H/3355/001	H/13/00519/004	MEDA PHARMA GMBH & CO. KG	SI
Dymista 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija azelastinijev klorid/flutikazonpropionat	DE/H/3355/001	H/13/00519/002	MEDA PHARMA GMBH & CO. KG	SI

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Dymista Nasal Spray 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	DE/H/3355/001	MA 806/01601	MEDA PHARMACEUTICALS LIMITED	MT
DYMISTA NASAL SPRAY 137 MICROGRAMS / 50 MICROGRAMS PER ACTUATION NASAL SPRAY, SUSPENSION	DE/H/3355/001	PL 46302/0162	MYLAN PRODUCTS LIMITED	UK
Dymista Nasal Spray 137 micrograms / 50 micrograms per actuation Nasal Spray, Suspension	DE/H/3355/001	PA1332/045/001	MEDA HEALTH SALES IRELAND LIMITED	IE
Dymista Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3355/001	85237.00.00	MEDA PHARMA GMBH & CO. KG	DE
Dymista nefúði 137 míkrogrömm / 50 míkrogrömm í hverjum úðaskammti Nefúði, dreifa	DE/H/3355/001	IS/1/13/025/01	MEDA AB	IS
Dymista Neusspray 137 microgram/50 microgram, neusspray, suspensie	DE/H/3910/001	RVG 114215	MEDA PHARMA B.V.	NL
Dymista nosová aerodisperzia 137 mikrogramov / 50 mikrogramov v jednom	DE/H/3355/001	24/0055/13-S	MYLAN IRE HEALTHCARE LIMITED	SK

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vstreknutí nosová suspenzná aerodisperzia				
Dymista sprej za nos 137 mikrograma + 50 mikrograma po potisku sprej za nos, suspenzija	not available	HR-H-228449282	MYLAN HRVATSKA D.O.O.	HR
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3355/001	OGYI-T-22423/02	MYLAN EPD KFT.	HU
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3355/001	OGYI-T-22423/03	MYLAN EPD KFT.	HU
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3355/001	OGYI-T-22423/04	MYLAN EPD KFT.	HU
Dymista szuszpenziós orrspray 137 mikrogramm / 50 mikrogramm befűjásenként	DE/H/3355/001	OGYI-T-22423/01	MYLAN EPD KFT.	HU

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Dymista Ρινικό Εκνέφωμα 137 μικρογραμμάρια / 50 μικρογραμμάρια ανά ψεκασμό Ρινικό Εκνέφωμα, Εναιώρημα	DE/H/3355/001	021885	MEDA PHARMACEUTICALS S.A.	CY
Dymista Ρινικό Εκνέφωμα 137 μικρογραμμάρια / 50 μικρογραμμάρια ανά ψεκασμό Ρινικό Εκνέφωμα, Εναιώρημα	DE/H/3355/001	84307/7-08-2018	MEDA PHARMACEUTICALS S.A.	GR
Dymista, (137 mikrogramów + 50 mikrogramów)/dawkę donosową, aerozol do nosa, zawiesina	DE/H/3355/001	21388	MYLAN HEALTHCARE SP. Z.O.O.	PL
Dymista, næsespray, suspension	DE/H/3355/001	49785	MEDA AS	DK
Dymista® Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3355/001	2013080274	MEDA PHARMA GMBH & CO. KG	LU
Dymista137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/003	MEDA PHARMA SIA	LT

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Dymista137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/002	MEDA PHARMA SIA	LT
Dymista137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/001	MEDA PHARMA SIA	LT
Dymista137 mikrogramai/50 mikrogramų/dozėje nosies purškalas (suspensija)	DE/H/3355/001	LT/1/13/3227/004	MEDA PHARMA SIA	LT
Dymistalan 137 mikrogramų/50 mikrogramų nosnį sprej, suspenze	DE/H/3356/001	69/ 339/13-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Dymistalin Nasenspray 137 Mikrogramm / 50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3910/001	90467.00.00	MEDA PHARMA GMBH & CO. KG	DE
Dymistin 137 mikrogramų/50 mikrogramų nosnį sprej, suspenze	DE/H/3355/001	69/338/13-C	MYLAN IRE HEALTHCARE LIMITED	CZ
Dymistin Nasenspray 137 Mikrogramm / 50 Mikrogramm pro Sprühstoß	DE/H/3911/001	90468.00.00	MEDA PHARMA GMBH & CO. KG	DE

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Nasenspray, Suspension				
Dymistin Neusspray 137 microgram/50 microgram, neusspray, suspensie	DE/H/3911/001	RVG 114221	MEDA PHARMA B.V.	NL
Dyvistalin 125 mikrogram/50 mikrogram/sprayning nässpray, suspension	DE/H/3356/001	47085	MEDA AB	SE
Dyvistanil 137 mcg/50 mcg/dose Solution pour pulvérisation nasale	DE/H/3356/001	2013080276	MEDA PHARMA GMBH & CO. KG	LU
Dyvistanil Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3356/001	2013080276	MEDA PHARMA GMBH & CO. KG	LU
Dyvistanil Nasenspray 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3356/001	85238.00.00	MEDA PHARMA GMBH & CO. KG	DE
Synaze 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3356/001	11004/2018/01	MEDA PHARMA GMBH & CO. KG	RO

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Synaze 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3356/001	11004/2018/02	MEDA PHARMA GMBH & CO. KG	RO
Synaze 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3356/001	11004/2018/03	MEDA PHARMA GMBH & CO. KG	RO
Synaze 137 micrograme/50 micrograme/doza spray nazal, suspensie	DE/H/3356/001	11004/2018/04	MEDA PHARMA GMBH & CO. KG	RO
SYNAZE 137 microgrammes/50 microgrammes, suspension pour pulvérisation nasale	DE/H/3356/001	34009 275 632 8 7	MEDA PHARMA SAS	FR
SYNAZE 137 microgrammes/50 microgrammes, suspension pour pulvérisation nasale	DE/H/3356/001	34009 275 633 4 8	MEDA PHARMA SAS	FR
Synaze 137 microgramos/50 microgramos /aplicación, suspensión para pulverización nasal	DE/H/3356/001	76619	MYLAN IRE HEALTHCARE LIMITED	ES

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
Synaze 137 mikrogram / 50 mikrogram per spray Nesespray, suspensjon	DE/H/3356/001	11-8687	MEDA AS	NO
Synaze 137 Mikrogramm/50 Mikrogramm pro Sprühstoß Nasenspray, Suspension	DE/H/3356/001	1-31923	MEDA PHARMA GMBH	AT
Synaze 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija azelastinijev klorid/flutikazonpropionat	DE/H/3356/001	H/13/01478/001	MEDA PHARMA GMBH & CO. KG	SI
Synaze 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija azelastinijev klorid/flutikazonpropionat	DE/H/3356/001	H/13/01478/002	MEDA PHARMA GMBH & CO. KG	SI
Synaze 137 mikrogramov/50 mikrogramov na vpih pršilo za nos, suspenzija azelastinijev klorid/flutikazonpropionat	DE/H/3356/001	H/13/01478/003	MEDA PHARMA GMBH & CO. KG	SI
Synaze 137 mikrogramov/50 mikrogramov na vpih	DE/H/3356/001	H/13/01478/004	MEDA PHARMA GMBH & CO. KG	SI

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pršilo za nos, suspenzija azelastinijev klorid/flutikazonpropionat				
Synaze sprej za nos 137 mikrograma + 50 mikrograma po potisku sprej za nos, suspenzija	not available	HR-H-666630000	MYLAN HRVATSKA D.O.O.	HR
Азекорт 137 микрограма/50 микрограма на доза спрей за нос, суспензия	DE/H/3356/001/DC	20130144	MEDA PHARMA GMBH & CO. KG	BG
Димиста 137 микрограма/50 микрограма на доза спрей за нос, суспензия	DE/H/3355/001/DC	20130142	MEDA PHARMA GMBH & CO. KG	BG