



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2024
EMA/167330/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ipratropium / xylometazoline

Procedure No. PSUSA/00009201/202308



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
Otrivin Duo 0,5 mg/ml + 0,6 mg/ml Nasenspray, Lösung	SE/H/0848/001	1-28286	GSK-GEBO CONSUMER HEALTHCARE GMBH	AT
Otrivine Duo 0,5 mg/ml + 0,6 mg/ml, neusspray, oplossing	SE/H/0848/001	BE335273	HALEON BELGIUM	BE
Otrivine Duo 0,5 mg/ml + 0,6 mg/ml, Nasenspray, Lösung Xylometazolinhydrochlorid/Ipratropiumbromid	SE/H/0848/001	BE335273	HALEON BELGIUM	BE
Otrivine Duo 0,5 mg/ml + 0,6 mg/ml, solution pour pulvérisation nasale	SE/H/0848/001	BE335273	HALEON BELGIUM	BE
Otrivin Advance 0,5 mg/ml + 0,6 mg/ml ρινικό εκνέφωμα, διάλυμα	SE/H/0848/001	21927	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	CY
Otrivin Rhinostop 0,5 mg/ml + 0,6 mg/ml nosní sprej, roztok	SE/H/0848/001	69/070/09-C	HALEON CZECH REPUBLIC S.R.O.	CZ
Otrivin Comp, næsespray, opløsning	SE/H/0848/001	43140	HALEON DENMARK APS	DK
Zymelin Plus, næsespray, opløsning	SE/H/0638/001	39815	ORIFARM HEALTHCARE A/S	DK
Otrivin Total, 0,5 mg/ml + 0,6 mg/ml ninasprei, lahus	SE/H/0848/001	614208	GLAXOSMITHKLINE DUNGARVAN LIMITED	EE
Rhinovin Duo 0,5 mg/ml + 0,6 mg/ml solución para pulverización nasal	SE/H/0848/001	70803	HALEON SPAIN, S.A.	ES
Otrivin Comp 0,5 mg/ml + 0,6 mg/ml nässpray, lösning	SE/H/0848/001	24899	HALEON DENMARK APS	FI
Otrivin Comp 0,5 mg/ml + 0,6 mg/ml nenäsumute, liuos	SE/H/0848/001	24899	HALEON DENMARK APS	FI
XYLOMÉTAZOLINE/IPRATROPIUM ACINO 0,5 mg/0,6 mg par mL, solution pour pulvérisation nasale	HR/H/0175/001/DC	34009 302 443 0 2	ACINO FRANCE SAS	FR

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Otrivin Advance 0,5 mg/ml + 0,6 mg/ml ρινικό εκνέφωμα, διάλυμα	SE/H/0848/001	2825001	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR
Ksilometazolinklorid/ipratropijev bromid Acino 0,5 mg/ml + 0,6 mg/ml sprej za nos, otopina	HR/H/0175/001/DC	HR-H-735131331	ACINO FRANCE SAS	HR
Nasoryl 0,5 mg/ml + 0,6 mg/ml sprej za nos, otopina	not available	HR-H-467318572	JADRAN-GALENSKI LABORATORIJ D.D.	HR
Nasoryl M 0,5 mg/ml + 0,6 mg/ml sprej za nos, otopina	not available	HR-H-942729742	JADRAN-GALENSKI LABORATORIJ D.D.	HR
Otrivin Komplex 0,5 mg/ml + 0,6 mg/ml oldatos orrspray	SE/H/0848/001	OGYI-T-20972/01	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Otrivine Extra Dual Relief 0.5mg/ml + 0.6mg/ml nasal spray, solution	SE/H/0848/001	PA0678/131/001	HALEON IRELAND LIMITED	IE
Otrivin Comp 0,5 mg/ml + 0,6 mg/ml nefúði, lausn	SE/H/0848/001	IS/1/08/074/01	HALEON DENMARK APS	IS
Rinazina Doppia Azione 0,5 mg/ml + 0,6 mg/ml spray nasale, soluzione	SE/H/0848/001	039064011	HALEON ITALY S.R.L.	IT
OtriDuo 0,5 mg/0,6 mg/ml nosies purškalas, tirpalas	SE/H/0848/001	LT/1/09/1681/001	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT
Otrivine Duo 0,5 mg/ml + 0,6 mg/ml, solution pour pulvérisation nasale	SE/H/0848/001	2011081238	HALEON BELGIUM	LU
Otrivin Total 0,5 mg/ml+0,6 mg/ml deguna aerosols, šķidums.	SE/H/0848/001	08-0334	GLAXOSMITHKLINE DUNGARVAN LIMITED	LV
Otrivine Extra Dual Relief 0.5 mg/ml + 0.6 mg/ml nasal spray, solution	SE/H/0848/001	MA1177/01001	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	MT
Otrivin Duo Xylometazolinehydrochloride & Ipratropiumbromide, 0,5/0,6 mg/ml, neusspray, oplossing	SE/H/0848/001	RVG 102338	HALEON NETHERLANDS B.V.	NL

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Otrivin Comp 0,5 mg/ml + 0,6 mg/ml nesespray, oppløsning	SE/H/0848/001	08-5834	HALEON DENMARK APS	NO
Zycomb 0,5 mg/ml + 0,6 mg/ml nesespray, oppløsning	SE/H/0638/001	06-4327	ORIFARM HEALTHCARE A/S	NO
Otrivin ipra MAX, (0,5 mg + 0,6 mg)/ml, aerosol do nosa, roztwór	SE/H/0848/001	15271	GLAXOSMITHKLINE CONSUMER HEALTHCARE SP. Z O.O.	PL
Nasitrim Duoeffect 0,5 mg/ml + 0,6 mg/ml Solução para pulverização nasal	18/H/0079/001	5772504	CUIDAFARMA, LDA.	PT
Vibrocil ActilongDuo, 0,5 mg/ml + 0,6 mg/ml, solução para pulverização nasal	SE/H/0848/001	5155056	HALEON PORTUGAL, LDA	PT
VIBROCIL DUO 0,5 mg/ml + 0,6 mg/ml spray nazal, soluție	SE/H/0848/001	4350/2012/01	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	RO
Otrivin Comp 0,5 mg/ml + 0,6 mg/ml nässpray, lösning	SE/H/0848/001	23529	HALEON DENMARK APS	SE
ZyComb 0,5 mg/ml + 0,6 mg/ml nässpray, løsnng	SE/H/0638/001	21928	ORIFARM HEALTHCARE A/S	SE
Maresyl Comb 0,5 mg/0,6 mg v 1 ml pršilo za nos, raztopina	not available	H/21/02864/001	JADRAN-GALENSKI LABORATORIJ D.D.	SI
Otrivin Duo 0,5 mg/0,6 mg v 1 ml pršilo za nos, raztopina	SE/H/0848/001	H/13/01198/002	GLAXOSMITHKLINE DUNGARVAN LIMITED	SI
Otrivin Duo 0,5 mg/0,6 mg v 1 ml pršilo za nos, raztopina	SE/H/0848/001	H/13/01198/001	GLAXOSMITHKLINE DUNGARVAN LIMITED	SI
Otrivin Complete 0,5 mg/ml + 0,6 mg/ml nosová roztoková aerodisperzia	SE/H/0848/001	69/0558/08-S	HALEON CZECH REPUBLIC S.R.O.	SK
Otrivine Extra Dual Relief 0.5 mg/ml + 0.6 mg/ml nasal spray, solution	SE/H/0848/001	PL 15545/0002	GLAXOSMITHKLINE DUNGARVAN LIMITED	XI