13 January 2022
EMA/683961/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: moxifloxacin (topical ophthalmic use)

Procedure no.: PSUSA/00002094/202105

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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
Moxifloxacin Micro Labs 5 mg/ml Augentropfen, Losung	DE/H/5167/001	140379	MICRO LABS GMBH	AT
KANAVIG 5 mg/ml Augentropfen	DE/H/1588/001	BE350707	NOVARTIS PHARMA N.V.	BE
KANAVIG 5 mg/ml collyre en solution	DE/H/1588/001	BE350707	NOVARTIS PHARMA N.V.	BE
KANAVIG 5 mg/ml oogdruppels, oplossing	DE/H/1588/001	BE350707	NOVARTIS PHARMA N.V.	BE
КСИФЛОДРОП 5 mg/ml капки за очи, разтвор	DK/H/2221/001	20140139	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
ВИГАМОКС 5 mg/ml, капки за очи, разтвор	DE/H/1588/001	20090230	NOVARTIS PHARMA GMBH	BG
Моксифлоксан 5 mg/ml, капки за очи, разтвор	not available	20150217	ANTIBIOTIC-RAZGRAD AD	BG
БИВОКСА 5 mg/ml капки за очи, разтвор	PT/H/1474/001	20160362	S.C. ROMPHARM COMPANY S.R.L.	BG
VIGAMOX 5 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/1588/001	20524	NOVARTIS IRELAND LIMITED	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
VIGAMOX 5 mg/ml OČNÍ KAPKY oční kapky, roztok	DE/H/1588/001	64/545/09-C	NOVARTIS S.R.O.,	CZ
Moxifloxacin Farmaprojects 5 mg/ml oční kapky, roztok	CZ/H/0963/001	64/335/19-C	FARMAPROJECTS S.A.U.	CZ
MOXIFLOXACIN® ALCON 5 mg/ml Augentropfen	DE/H/1588/001	72577.00.00	NOVARTIS PHARMA GMBH	DE
VIGAMOX 5 mg/ml Augentropfen	not available	56654.00.00	NOVARTIS PHARMA GMBH	DE
Moxifloxacin Micro Labs 5 mg/ml Augentropfen, Lösung	DE/H/5167/001	99474.00.00	MICRO LABS GMBH	DE
Moxifloxacin Farmaprojects 5 mg/ml Augentropfen, Lösung	CZ/H/0963/001	2204985.00.00	FARMAPROJECTS S.A.U.	DE
Xiflodrop, øjendråber, opløsning	DK/H/2221/001	50964	BAUSCH HEALTH IRELAND LIMITED	DK
Vigamox, øjendråber, opløsning	DE/H/1588/001	43034	NOVARTIS HEALTHCARE A/S	DK
VAMOCIN 5MG/ML, ØJENDRÅBER, OPLØSNING	DK/H/2219/001	50957	PHARMATHEN S.A.	DK

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Lifodrox 5 mg/ml silmatilgad, lahus	DK/H/2221/001	840514	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
VIGAMOX, 5 mg/ml silmatilgad, lahus	DE/H/1588/001	639009	SIA "NOVARTIS BALTICS"	EE
Flomixa 5 mg/ml silmatilgad, lahus	EE/H/0263/001	992719	NORD FARM SP. Z O.O.	EE
VIGAMOX 5 mg/ml colirio en solución	DE/H/1588/001	71.576	NOVARTIS FARMACÉUTICA S.A.	ES
Moxifloxacino Kern Pharma 5 mg/ml colirio en solución	not available	78.593	KERN PHARMA, S.L.	ES
Abimox 5 mg/ml colirio en solución	DK/H/2219/001	78338	TIEDRA FARMACEUTICA SL	ES
Moxifloxacino Farmaprojects 5 mg/ml colirio en solución	CZ/H/0963/001	85785	FARMAPROJECTS S.A.U.	ES
Vigamox 5 mg/ml ögondroppar, lösning	DE/H/1588/001	24834	NOVARTIS FINLAND OY	FI
Vigamox 5 mg/ml silmätipat, liuos	DE/H/1588/001	24834	NOVARTIS FINLAND OY	FI

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
VIGAMOX 5 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/1588/001	282120101	NOVARTIS (HELLAS) S.A.C.I.	GR
Tamvelier 5mg/mL οφθαλμικές σταγόνες, διάλυμα	DK/H/2219/001	27853/4-3-2020	PHARMATHEN INVESTMENTS GROUP LIMITED	GR
Moksacin 5 mg/ml kapi za oko, otopina	HR-H-460017128	HR-H-460017128	JADRAN-GALENSKI LABORATORIJ D.D.	HR
Vigamox 5 mg/ml oldatos szemcsepp	DE/H/1588/001	OGYI-T-22430/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Vigamox 5 mg/ml augndropar, lausn.	DE/H/1588/001	IS/1/08/066/01	NOVARTIS HEALTHCARE A/S	IS
VIGAMOX 5 mg/ml collirio, soluzione	DE/H/1588/001	039559012	NOVARTIS FARMA S.P.A.	IT
OXA 5 mg/ml collirio, soluzione.	not available	045272010	FARTO S.R.L. FARMACO BIOCHIMICO TOSCANO	IT
LIFODROX 5 mg/ml akių lašai (tirpalas)	DK/H/2221/001	LT/1/14/3520/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Vigamox 5 mg/ml akių lašai (tirpalas)	DE/H/1588/001	LT/1/09/1655/001	SIA "NOVARTIS BALTICS"	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
Ekara 5 mg/ml akių lašai (tirpalas)	PL/H/0413/001	LT/1/17/4133/001	POLPHARMA	LT
KANAVIG 5 mg/ml collyre en solution	DE/H/1588/001	2010030057	NOVARTIS PHARMA N.V.	LU
KANAVIG 5 mg/ml Augentropfen	DE/H/1588/001	2010030057	NOVARTIS PHARMA N.V.	LU
Lifodrox 5 mg/ml acu pilieni, šķīdums	DK/H/2221/001	14-0010	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
VIGAMOX 5 mg/ml acu pilieni, šķīdums	DE/H/1588/001	09-0283	SIA "NOVARTIS BALTICS"	LV
Ekara 5 mg/ml acu pilieni, šķīdums	PL/H/0413/001	17-0195	POLPHARMA	LV
VIGAMOX 5 mg/ml eye drops, solution	DE/H/1588/001	MA1249/01901	NOVARTIS IRELAND LIMITED	MT
VIGAMOX 5 mg/ml oogdruppels, oplossing	DE/H/1588/001	RVG 102202	NOVARTIS PHARMA B.V.	NL
Xiflodrop, 5 mg/ml, krople do oczu, roztwór	DK/H/2221/001	22167	BAUSCH HEALTH IRELAND LIMITED	PL

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VIGAMOX, 5 mg/ml, krople do oczu, roztwór	DE/H/1588/001	16016	NOVARTIS POLAND SP. Z O. O.	PL
Flomixa, 5 mg/ml, krople do oczu, roztwór	EE/H/0263/001	25646	NORD FARM SP. Z O.O.	PL
Monafox, 5 mg/mL, krople do oczu, roztwór	PL/H/0477/001	21729	ADAMED PHARMA S.A.	PL
Floxamic Neo, 5 mg/ml, krople do oczu, roztwór	PL/H/0413/001	24302	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
VIGAMOX 5 mg/ml colírio, solução	DE/H/1588/001	5218961	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Moxifloxacina Rompharm 5 mg/ml, colírio, solução	PT/H/1474/001	5688668	S.C. ROMPHARM COMPANY S.R.L.	PT
VIGAMOX 5 mg/ml picături oftalmice, soluţie	DE/H/1588/001	6924/2014/01	NOVARTIS PHARMA GMBH	RO
Moxifloxacină Rompharm 5 mg/ml picături oftalmice, soluţie	PT/H/1474/001	9348/2016/01	S.C. ROMPHARM COMPANY S.R.L.	RO
Vigamox 5 mg/ml ögondroppar, lösning	DE/H/1588/001	26789	NOVARTIS SVERIGE AB	SE

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MOKSIFLOKSACIN Apta 5 mg/ml kapljice za oko, raztopina	not available	H/19/02670/001	APTA MEDICA INTERNACIONAL D.O.O.	SI
VIGAMOX 5 mg/ml kapljice za oko, raztopina	DE/H/1588/001	H/09/01916/001	NOVARTIS PHARMA GMBH	SI
VIGAMOX 5 mg/ml očná roztoková instilácia	DE/H/1588/001	64/0450/09-S	NOVARTIS SLOVAKIA S.R.O.	SK
MOXIVIG 0.5%w/v eye drops, solution	DE/H/1588/001	PL 00101/1002	NOVARTIS PHARMACEUTICALS UK LIMITED	XI