



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2017
EMA/28753/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: moxifloxacin (topical ophthalmic use)

Procedure no.: PSUSA/00002094/201605



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
Floxamic, 5 mg/mL, krople do oczu, roztwór	DK/H/2219/001	21976	ZAKŁADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Floxitrat Ofta	DE/H/3817/001	21609	SANDOZ GMBH	PL
KANAVIG 5 mg/ml Augentropfen	DE/H/1588/001	2010030057	ALCON NV	LU
KANAVIG 5 mg/ml collyre en solution	DE/H/1588/001	2010030057	ALCON NV	LU
Lifodrox 5 mg/ml acu pilieni, šķīdums	DK/H/2221/001	14-0010	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LV
LIFODROX 5 mg/ml akių lašai (tirpalas)	DK/H/2221/001	LT/1/14/3520/001	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	LT
Lifodrox 5 mg/ml silmatilgad, lahus	DK/H/2221/001	840514	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	EE
Moksacin 5 mg/ml kapi za oko, otopina	not available	UP/I-530-09/10-01/535	BONIFARM D.O.O.	HR
Monafox, 5 mg/mL, krople do oczu, roztwór	DK/H/2220/001	21729	ADAMED	PL
Monafox, øjendråber, opløsning	DK/H/2220/001	50960	ADAMED	DK

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MOXIFLOXACIN ALCON 5 mg/ml Augentropfen	DE/H/1588/001	72577.00.00	ALCON PHARMA GMBH	DE
Moxifloxacin HEXAL 5 mg/ml Augentropfen	DE/H/3817/001	89474.00.00	HEXAL AG	DE
Moxifloxacin Sandoz 5mg/ml oldatos szemcsepp	DE/H/3817/001	OGYI-T-22540/01	SANDOZ HUNGÁRIA KFT	HU
MOXIFLOXACINA PHARMATHEN 5 MG/ML PICĂTURI OFTALMICE, SOLUȚIE	DK/H/2219/001	6203/2014/01	PHARMATHEN S.A.	RO
Moxifloxacin Sandoz	DE/H/3817/001	042612010	SANDOZ S.P.A.	IT
Moxifloxacin Kern Pharma 5 mg/ml colirio en solución	not available	78.593	KERN PHARMA, S.L.	ES
Moxifloxacin Kern Pharma 5 mg/ml colirio en solución	not available	78.593	KERN PHARMA, S.L.	ES
MOXIFLOXACINO PHARMATHEN 5 MG/ML COLIRIO EN SOLUCIÓN	DK/H/2219/001	78338	PHARMATHEN S.A.	ES
MOXIFLOXACINO SANDOZ 5 MG/ML COLIRIO EN SOLUCION	DE/H/3817/001	78403	SANDOZ FARMACÉUTICA, S.A.	ES

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MOXIVIG 0.5%w/v eye drops, solution	DE/H/1588/001	PA 290/79/1	ALCON LABORATORIES (UK) LTD	IE
MOXIVIG 0.5%w/v eye drops, solution	DE/H/1588/001	PL 00649/0378	ALCON LABORATORIES (UK) LTD	UK
Tamvelier 5mg/ml οφθαλμικές σταγόνες, διάλυμα	DK/H/2219/001	10270/9-2-2015	PHARMATHEN HELLAS S.A.	GR
VAMOCIN 5MG/ML, ØJENDRÅBER, OPLØSNING	DK/H/2219/001	50957	PHARMATHEN S.A.	DK
VIGAMOX 5 mg/ml acu pilieni, šķīdums	DE/H/1588/001	09-0283	SA ALCON-COUVREUR NV	LV
VIGAMOX 5 mg/ml akių lašai (tirpalas)	DE/H/1588/001	LT/1/09/1655/001	SA ALCON-COUVREUR NV	LT
VIGAMOX 5 mg/ml Augentropfen	DE/H/1588/001	56654.00.00	ALCON PHARMA GMBH	DE
VIGAMOX 5 mg/ml colirio en solución	DE/H/1588/001	71576	ALCON CUSI, S.A	ES
VIGAMOX 5 mg/ml colírio, solução	DE/H/1588/001	5218961	ALCON PORTUGAL - PRODUTOS E EQUIPAMENTOS OFTALMOLÓGICOS, LDA.	PT

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VIGAMOX 5 mg/ml collirio, soluzione	DE/H/1588/001	039559012	ALCON ITALIA S.P.A.	IT
VIGAMOX 5 mg/ml eye drops, solution	DE/H/1588/001	015/01301	SA ALCON-COUVREUR NV	MT
VIGAMOX 5 mg/ml kapljice za oko, raztopina	DE/H/1588/001	H/09/1916/001	SA ALCON-COUVREUR NV	SI
VIGAMOX 5 mg/ml očná roztoková instilácia	DE/H/1588/001	64/0450/09-S	SA ALCON-COUVREUR NV	SK
VIGAMOX 5 mg/ml OČNÍ KAPKY oční kapky, roztok	DE/H/1588/001	64/545/09-C	ALCON PHARMACEUTICALS, CZECH REPUBLIC SRO	CZ
Vigamox 5 mg/ml ögondroppar, lösning	DE/H/1588/001	26789	ALCON NORDIC A/S	SE
Vigamox 5 mg/ml oldatos szemcsepp	DE/H/1588/001	OGYI-T-22430/01	ALCON HUNGARIAN LTD.	HU
VIGAMOX 5 mg/ml oogdruppels, oplossing	DE/H/1588/001	RVG 102202	ALCON NEDERLAND BV	NL
VIGAMOX 5 mg/ml picături oftalmice, soluție	DE/H/1588/001	1749/2009/01	ALCON PHARMA GMBH	RO

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VIGAMOX 5 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/1588/001	20524	ALCON LABORATORIES HELLAS S.A.	CY
VIGAMOX 5 mg/ml οφθαλμικές σταγόνες, διάλυμα	DE/H/1588/001	31008/26-05-2010	ALCON LABORATORIES HELLAS S.A.	GR
Vigamox 5 mg/ml augndropar, lausn.	DE/H/1588/001/DC	IS/1/08/066/01	ALCON NORDIC A/S	IS
VIGAMOX 5 mg/ml silmatipat, liuos	DE/H/1588/001	24834	ALCON NORDIC A/S	FI
VIGAMOX, 5 mg/ml silmatilgad, lahus	DE/H/1588/001	639009	SA ALCON-COUVREUR NV	EE
VIGAMOX, 5 mg/ml, krople do oczu, roztwór	DE/H/1588/001	16016	ALCON POLSKA SP. Z.O.O	PL
Vigamox, øjendråber, opløsning	DE/H/1588/001	43034	ALCON NORDIC A/S	DK
Xiflodrop 5 mg/ml oldatos szemcsepp	DK/H/2221/001	OGYI-T-22624/01	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	HU
XIFLODROP 5mg/ml očná roztoková instilácia	DK/H/2221/001	64/0100/14-S	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	SK

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Xiflodrop, 5 mg/ml, krople do oczu, roztwór	DK/H/2221/001	22167	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	PL
Xiflodrop, øjendråber, opløsning	DK/H/2221/001	50964	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	DK
ВИГАМОКС 5 mg/ml, капки за очи, разтвор	DE/H/1588/001	II-4951	ALCON PHARMA GMBH	BG
КСИФЛОДРОП 5 mg/ml капки за очи, разтвор	DK/H/2221/001	20140139	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
Моксифлоксан 5 mg/ml, капки за очи, разтвор	not available	20150217	ANTIBIOTIC-RAZGRAD AD	BG