



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2024
EMA/121791/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): levofloxacin (ocular use)

Procedure No. PSUSA/00010768/202310



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
Oftaquix 5 mg/ml Augentropfen, Lösung	FI/H/0989/001	1-24655	SANTEN OY	AT
Οφτακυικς 5 mg/ml очни капки Oftaquix 5 mg/ml eye drops	not available	20040266	SANTEN OY	BG
Lexavon eye drops solution/Rafarm 5mg/mL	PT/H/821/01/DC	021948	RAFARM SA.	CY
Levofloxacin/RAFARM [PF] οφθαλμικές σταγόνες, διάλυμα 5mg/ml	NL/H/4549/001/DC	023328	RAFARM SA.	CY
Oftaquix 5 mg/ml oční kapky, roztok	FI/H/0989/001	64/175/05-C	SANTEN OY	CZ
Oftaquix sine 5 mg/ml Augentropfen im Einzeldosisbehältnis	FI/H/989/02	67435.00.00	SANTEN OY	DE
Oftaquix 5 mg/ml Augentropfen, Lösung	FI/H/0989/001	53538.00.00	SANTEN OY	DE
Oftaquix	FI/H/989/02	40612	SANTEN OY	DK
Oftaquix, øjendråber, opløsning	FI/H/0989/001	33160	SANTEN OY	DK
Levofloxacin Actavis 5 mg/ml silmatilgad, lahus	SE/H/1715/001	905516	TEVA B.V	EE
Oftaquix 5 mg/ml silmatilgad, lahus	FI/H/0989/001	472305	SANTEN OY	EE
Levofloxacin UNIMED PHARMA 5 mg/ml silmatilgad, lahus	HU/H/0449/001	933917	UNIMED PHARMA SPOL.S R.O.	EE
Oftaquix 5 mg/ml silmätipat, liuos kerta-annospipetissä	FI/H/989/02	23157	SANTEN OY	FI
OFTAQUIX 5 mg/ml ögondroppar, lösning i endosbehållare	FI/H/989/02	23157	SANTEN OY	FI
Oftaquix 5 mg/ml -silmätipat	FI/H/989/01	16992	SANTEN OY	FI
Oftaquix 5 mg/ml ögondroppar	FI/H/989/01	16992	SANTEN OY	FI
LEXAVON 5 mg/ml οφθαλμικές σταγόνες, διάλυμα	PT/H/0821/001	86959/28-09-2021	RAFARM SA.	GR

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Levofloxacin/RAFARM [PF] οφθαλμικές σταγόνες, διάλυμα 5mg/ml	NL/H/4549/001	52435/19-05-2020	RAFARM SA.	GR
Oftaquix 5 mg/ml oldatos szemcsepp	FI/H/0989/001	OGYI-T-10257/01	SANTEN OY	HU
Levofloxacin UNIMED PHARMA 5 mg/ml oldatos szemcsepp	HU/H/0449/001	OGYI-T-23155/01	UNIMED PHARMA SPOL.S R.O.	HU
Oftaquix 5 mg/ml augndropar, lausn stakskammtailát	FI/H/989/02	IS/1/07/020/01	SANTEN OY	IS
Oftaquix 5 mg/ml augndropar	FI/H/989/01	IS/1/02/003/01	SANTEN OY	IS
FLOXANA 5 mg/ml collirio, soluzione	not available	045073018	GENETIC SPA	IT
FLOXANA 5 mg/ml collirio, soluzione	not available	045073020	GENETIC SPA	IT
PETAS 5 mg/ml collirio, soluzione	not available	045075013	GENETIC SPA	IT
PETAS 5 mg/ml collirio, soluzione	not available	045075025	GENETIC SPA	IT
SOCIN 5 mg/ml collirio, soluzione	not available	045078019	GENETIC SPA	IT
SOCIN 5 mg/ml collirio, soluzione	not available	045078021	GENETIC SPA	IT
Levodrop 5 mg/ml collirio, soluzione	PT/H/0822/001	042149017	ALFA INTES INDUSTRIA TERAPEUTICA SPLENDORE VIA FRATELLI	IT
Oftaquix 5 mg/ml collirio, soluzione, contenitore monodose	FI/H/989/02	035728031/M	SANTEN OY	IT
Oftaquix 5 mg/ml collirio, soluzione, contenitore monodose	FI/H/989/02	035728029/M	SANTEN OY	IT
Oftaquix 5 mg/ml collirio, soluzione, contenitore monodose	FI/H/989/02	035728043/M	SANTEN OY	IT
Oftaquix 5 mg/ml collirio, soluzione, contenitore monodose	FI/H/989/02	035728056/M	SANTEN OY	IT

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Oftaquix 5 mg/ml collirio, soluzione	FI/H/0989/001	035728017	SANTEN OY	IT
FLOXSINE 5 mg/ml collirio soluzione	NL/H/4549/001	048367015	BRUSCHETTINI S.R.L	IT
DOCLEVO 5 mg/ml collirio, soluzione	not available	047432012	DOC GENERICI S.R.L.	IT
Levodrop 5 mg/ml collirio, soluzione	PT/H/0822/001	042149017	ALFA INTES INDUSTRIA TERAPEUTICA SPLENDORE VIA FRATELLI	IT
Visuflox 5 mg/ml collirio, soluzione	PT/H/1495/001	044459016	VISUFARMA SPA	IT
KINOFTA 5 mg/ml collirio, soluzione	PT/H/1738/001	045517012	OFFHEALTH S.P.A.	IT
FLOXISTILL 5 mg/ml collirio soluzione	PT/H/1360/001	044071013	BRUSCHETTINI S.R.L	IT
Levofloxacin Actavis 5 mg/ml akių lašai (tirpalas)	SE/H/1715/001	LT/1/16/3901/001	TEVA B.V	LT
OFTAQUIX 5 mg/ml akių lašai (tirpalas)	FI/H/0989/001	LT/1/05/0325/001	SANTEN OY	LT
Levofloxacin UNIMED PHARMA 5 mg/ml akių lašai (tirpalas)	HU/H/0449/001	LT/1/17/4044/001	UNIMED PHARMA SPOL.S R.O.	LT
Levofloxacin Actavis 5 mg/ml acu pilieni, šķīdums	SE/H/1715/001	16-0090	TEVA B.V	LV
Oftaquix 5 mg/ml acu pilieni, šķīdums	FI/H/0989/001	05-0196	SANTEN OY	LV
Levofloxacin UNIMED PHARMA 5 mg/ml acu pilieni, šķīdums	HU/H/0449/001	17-0057	UNIMED PHARMA SPOL.S R.O.	LV
Levofloxacin Rafarm zonder conserveermiddel 5 mg/ml oogdruppels, oplossing	NL/H/4549/001	RVG123923	RAFARM SA.	NL
Levofloxacin Genoptim, 5 mg/ml, krople do oczu, roztwór	PT/H/1368/001	23141	SYNOPTIS PHARMA SP Z O O	PL
Levofloxacin UNIMED PHARMA, 5 mg/ml, krople do oczu, roztwór	HU/H/0449/001	24081	UNIMED PHARMA SPOL.S R.O.	PL
Oftaquix, 5 mg/ml, krople do oczu, roztwór	not available	10825	SANTEN OY	PL

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Oftaquix sine, 5 mg/ml, krople do oczu, roztwór w pojemniku jednodawkowym	not available	17128	SANTEN OY	PL
Levomer, 5 mg/ml, krople do oczu, roztwór	PT/H/1495/001	23616	ADAMED PHARMA S.A.	PL
Levofloxacin Velka Hellas 5 mg/ml colírio, solução	PT/H/1495/001	5691118	VELKA HELLAS S.A.	PT
Levofloxacin Optacare 5 mg/ml colírio	PT/H/0822/001	5593173	NTC SRL	PT
Levofloxacin Optacare 5 mg/ml colírio	PT/H/0822/001	5593173	NTC SRL	PT
Levofloxacin Rafarm 5 mg/ml colírio, solução	PT/H/0821/001	5601257	RAFARM SA.	PT
Oftaquix 5 mg/ml colírio, solução	FI/H/0989/001	4041786	SANTEN OY	PT
Xeflox 5 mg/ml colírio	PT/H/1738/001	5831045	DAVI II - FARMACÊUTICA, S.A.	PT
Levofloxacin Optacare 5 mg/ml colírio	PT/H/0822/001	5593173	NTC SRL	PT
Levoftal	NL/H/4549/001	5800826	RAFARM SA.	PT
Levofloxacin Bruschetti 5 mg/ml colírio, solução	PT/H/1360/001	5666540	BRUSCHETTINI S.R.L	PT
Oftaquix 5 mg/ml picături oftalmice, soluție.	FI/H/0989/001	9806/2017/01	SANTEN OY	RO
Levofloxacin Actavis 5 mg/ml ögondroppar, lösning	SE/H/1715/001	52248	ACTAVIS GROUP PTC EHF.	SE
Oftaquix 5 mg/ml ögondroppar, lösning i endosbehållare	FI/H/989/02	25042	SANTEN OY	SE
Oftaquix 5 mg/ml ögondroppar, lösning	FI/H/0989/001	17994	SANTEN OY	SE
Levofloksacin UNIMED PHARMA 5 mg/ml kapljice za oko, raztopina	HU/H/0449/001	H/17/02355/001	UNIMED PHARMA SPOL.S R.O.	SI
Oftaquix 5 mg/ml očná roztoková instilácia	FI/H/0989/001	64/0180/05-S	SANTEN OY	SK
Eyflox 5 mg/ml eye drops, solution	not available	PL35533/0137	ASPIRE PHARMA LIMITED	XI

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Oxalux Unit Dose 5 mg/ml eye drops, solution in single-dose container	not available	PL 25617/0002	KESTREL OPHTHALMICS LTD	XI
Oftaquix Unit Dose 5 mg/ml eye drops	FI/H/989/02	16058/0007	SANTEN OY	XI
Levofloxacin 5mg/ml Eye Drops Solution	not available	PL 0142/0946	ACCORD-UK LIMITED	XI
Levofloxacin 5 mg/ml eye drops solution	PT/H/1495/001	PL35533/0069	ASPIRE PHARMA LIMITED	XI
Oftaquix 5 mg/ml eye drops, solution	FI/H/0989/001	PL 16058/0006	SANTEN OY	XI