



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2024
EMA/459239/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ofloxacin (topical use)

Procedure No. PSUSA/00002204/202404



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
Otiflox 1,5 mg/0,5 ml Ohrentropfen im Einzeldosisbehältnis	NL/H/2980/001	135917	PHARMA STULLN GMBH	AT
Ofloxacin Stulln 3 mg/ml Augentropfen	NL/H/2392/001	1-31663	PHARMA STULLN GMBH	AT
Floxal® EDO® 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	not available	141589	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	AT
Ofloxacin Stulln 3 mg/ml Augentropfen im Einzeldosisbehältnis	NL/H/2393/001	1-31664	PHARMA STULLN GMBH	AT
Floxal 3 mg/g Augensalbe	not available	1-23679	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	AT
VisioFlox 3 mg/g Augensalbe	AT/H/0767/001	138958	OMNIVISION GMBH	AT
Ofloxa-Vision 3 mg/g Augensalbe	AT/H/0544/001	137160	OMNIVISION GMBH	AT
Floxal® - 3 mg/ml Augentropfen, Lösung	not available	1-19054	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	AT
Ofloxa-Vision sine 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	AT/H/0433/001/DC	1-31917	OMNIVISION GMBH	AT
Trafloxal 3 mg/g pommade ophtalmique	not available	BE156825	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal 3 mg/g oogzalf	not available	BE156825	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal 3 mg/g Augensalbe	not available	BE156825	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal EDO 3 mg/ml collyre en solution en récipient unidose	not available	BE227141	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal EDO 3 mg/ml oogdruppels, oplossing in verpakking voor	not available	BE227141	BAUSCH + LOMB IRELAND LIMITED	BE

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éénmalig gebruik				
Trafloxal EDO 3mg/ml Augentropfen in Einzeldosisbehältnis	not available	BE227141	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal 3 mg/ml collyre en solution	not available	BE153054	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal 3 mg/ml oogdruppels, oplossing	not available	BE153054	BAUSCH + LOMB IRELAND LIMITED	BE
Trafloxal 3 mg/ml Augentropfen	not available	BE153054	BAUSCH + LOMB IRELAND LIMITED	BE
Флоксал 3 mg/ml капли за очи, разтвор	not available	20060871	BAUSCH + LOMB IRELAND LIMITED	BG
UNIFLOX 0,3 % eye/ear drops, solution	not available	20020082	UNIMED PHARMA SPOL.S R.O.	BG
Флоксал 3 mg/g маз за очи	not available	20070008	BAUSCH + LOMB IRELAND LIMITED	BG
Ofloxacin-POS 3 mg/ml oční kapky, roztok	NL/H/2482/001	64/686/12-C	URSAPHARM SPOL. S.R.O.	CZ
Ofloxacin UNIMED PHARMA 3 mg/ml oční/ušní kapky, roztok	not available	64/324/06-C	UNIMED PHARMA SPOL.S R.O.	CZ
Floxal 3 mg/g oční mast	not available	64/368/00-C	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	CZ
Floxal 3 mg/ml oční kapky, roztok	not available	64/367/00-C	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	CZ
Ofloxa-Vision Kombi-Packung 3 mg/ml Augentropfen, Lösung und 3 mg/g Augensalbe	DE/H/6413/001	2204526.00.00	OMNIVISION GMBH	DE
Ofloxacin-Ophtal 3 mg/g Augensalbe	not available	89480.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ofloxacin-Ophtal 3 mg/g Augensalbe	not available	89480.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Floxal EDO 3 mg/ml Augentropfen, Lösung	not available	35778.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ofloxacin-POS 3 mg/ml Augentropfen	NL/H/2482/001	86497.00.00	URSAPHARM ARZNEIMITTEL GMBH	DE
Floxal® 3 mg/g	not available	15583.00.01	DR. GERHARD MANN CHEM.-	DE

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Augensalbe			PHARM. FABRIK GMBH	
Ofloxacin-ratiopharm 3 mg/ml Augentropfen	NL/H/2394/001	85248.00.00	RATIOPHARM GMBH	DE
Ofloxamed® 3 mg/ml Augentropfen, Lösung	SE/H/1285/001	89384.00.00	MIBE GMBH ARZNEIMITTEL	DE
Ofloxacin Devatis 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	NL/H/2858/001	89755.00.00	DEVATIS GMBH	DE
Ofloxacin Devatis 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	NL/H/2858/001	89755.00.00	DEVATIS GMBH	DE
Ofloxacin Devatis 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	NL/H/2858/001	89755.00.00	DEVATIS GMBH	DE
Ofloxacin Devatis 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	NL/H/2858/001	89755.00.00	DEVATIS GMBH	DE
Ofloxa-Vision 3 mg/ml Augentropfen, Lösung	NL/H/2392/001	85247.00.00	OMNIVISION GMBH	DE
Ofloxacin-ratiopharm 3 mg/ml Augentropfen im Einzeldosisbehältnis	NL/H/2393/001	85249.00.00	RATIOPHARM GMBH	DE
Ofloxacin-Ophtal® 3 mg/ml Augentropfen, Lösung	not available	89479.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ofloxamed® 3 mg/ml Augentropfen, Lösung	SE/H/1285/001	89384.00.00	MIBE GMBH ARZNEIMITTEL	DE
Ofloxacin Stulln 3 mg/1 ml Augentropfen	not available	83541.00.00	PHARMA STULLN GMBH	DE
Ofloxa-Vision 3 mg/g Augensalbe	AT/H/0544/001	92145.00.00	OMNIVISION GMBH	DE
Ofloxacin Stulln® UD 3 mg/1 ml Augentropfen	not available	79808.00.00	PHARMA STULLN GMBH	DE
Floxa® 3 mg/ml	not available	15583.00.00	DR. GERHARD MANN CHEM.-	DE

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Augentropfen			PHARM. FABRIK GMBH	
Ofloxa-Vision sine 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	AT/H/0433/001/DC	86236.00.00	OMNIVISION GMBH	DE
Ofloxacin-Ophtal® sine 3 mg/ml Augentropfen, Lösung	not available	45031.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ofloxacino POS 3 mg/ml colirio en solución	NL/H/2482/001	81022	BRILL PHARMA S.L.	ES
Ofloxacino POS 3 mg/ml colirio en solución	NL/H/2482/001	81022	BRILL PHARMA S.L.	ES
OFLOXAVIS 3 mg/ml colirio en solución	NL/H/2392/001	77631	PHARMA STULLN GMBH	ES
EXOCIN 3 mg/ml colirio en solución	not available	62.560	ABBVIE SPAIN S.L.U.	ES
EXOCIN 3 mg/ml, silmätipat, liuos	not available	11691	ABBVIE OY	FI
OFLOXACINE VIATRIS 1,5 mg/0,5 ml, solution auriculaire en récipient unidose	not available	34009 302 368 3 3	VIATRIS SANTE	FR
EXOCINE 0,3 POUR CENT, collyre	not available	34009 331 708 0 6	ABBVIE	FR
OFLOXACINE VIATRIS 1,5 mg/0,5 ml, solution auriculaire en récipient unidose	not available	34009 302 368 3 3	VIATRIS SANTE	FR
OFLOXACINE VIATRIS 1,5 mg/0,5 ml, solution auriculaire en récipient unidose	not available	34009 302 368 3 3	VIATRIS SANTE	FR
MONOOX 1,5 mg/0,5 ml, collyre en solution en récipient unidose	not available	34009 266 191 2 1	HORUS PHARMA	FR
MONOOX 1,5 mg/0,5 ml, collyre en solution en récipient unidose	not available	34009 266 192 9 9	HORUS PHARMA	FR

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MONOOX 1,5 mg/0,5 ml, collyre en solution en récipient unidose	not available	34009 583 313 0 5	HORUS PHARMA	FR
MONOOX 1,5 mg/0,5 ml, collyre en solution en récipient unidose	not available	34009 583 312 4 4	HORUS PHARMA	FR
OFLOCET 1,5 mg/0,5 ml, solution auriculaire en récipient unidose	not available	34009 339 863 5 3	SANOFI WINTHROP INDUSTRIE	FR
QUINOFREE 1,5 mg/ 0,5 ml, collyre en récipient unidose	not available	34009 499 526 7 0	LABORATOIRES THEA	FR
QUINOFREE 1,5 mg/ 0,5 ml, collyre en récipient unidose	not available	34009 579 206 9 2	LABORATOIRES THEA	FR
QUINOFREE 1,5 mg/ 0,5 ml, collyre en récipient unidose	not available	34009 579 207 5 3	LABORATOIRES THEA	FR
OXATREX, Οφθαλμικές σταγόνες, διάλυμα μιας δόσης 1,5 mg / 0,5 ml (0,3% W/V ή 3 mg/ 1 ml)	not available	105898/10-10-2022	ZWITTER PHARMACEUTICALS ΕΠΕ	GR
Exocin 3 mg/ml οφθαλμικές σταγόνες, διάλυμα	not available	73326/16-07-2020	ABBVIE PHARMACEUTICALS S.A.	GR
Uniflox 3 mg/ml kapi za oko, otopina	not available	HR-H-415727029	UNIMED PHARMA SPOL.S R.O.	HR
Uniflox 3 mg/ml kapi za oko, otopina	not available	HR-H-415727029	UNIMED PHARMA SPOL.S R.O.	HR
Ofloxacin Unimed Pharma 3mg/ml oldatos szemcsepp	not available	OGYI-T-22718/01	UNIMED PHARMA SPOL.S R.O.	HU
Ofloxacin Unimed Pharma 3mg/ml oldatos szemcsepp	not available	OGYI-T-22718/02	UNIMED PHARMA SPOL.S R.O.	HU
Floxxal 3 mg/ml oldatos szemcsepp	not available	OGYI-T-4928/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	HU

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FloXal 3 mg/g szemkenőcs ofloxacin	not available	OGYI-T-4929/01	BAUSCH + LOMB IRELAND LIMITED	HU
EXOCIN (Ofloxacin) 0.3% w/v Eye Drops Solution	not available	PA1824/14/1	ABBVIE LIMITED	IE
MultifloXofta 3 mg/ml collirio, soluzione	PT/H/1471/001	045392014	FIDIA FARMACEUTICI S.P.A	IT
MultifloXofta 3 mg/ml collirio, soluzione	PT/H/1471/001	045392026	FIDIA FARMACEUTICI S.P.A	IT
MultifloXofta 3 mg/ml collirio, soluzione	PT/H/1471/001	045392038	FIDIA FARMACEUTICI S.P.A	IT
EXOCIN 3 mg/ml collirio, soluzione	not available	027234032	ABBVIE S.R.L.	IT
VisuAb, 3 mg/ml collirio, soluzione	NL/H/2482/001	044623015	VISUFARMA SPA	IT
MONOFLOXOFTA 0,3% collirio, soluzione.	not available	039901018	FIDIA FARMACEUTICI S.P.A	IT
DUNAFLOT 3 mg/ml collirio, soluzione	not available	044951010	BIODUE S.P.A	IT
DUNAFLOT 3 mg/ml collirio, soluzione	not available	044951022	BIODUE S.P.A	IT
OcuFloX 3 mg/g unguento oftalmico	AT/H/0767/001	045984010	OMNIVISION ITALIA S.R.L.	IT
OFLATON 3 mg/ml collirio, soluzione.	not available	044949028	GENETIC SPA	IT
OFLATON 3 mg/ml collirio, soluzione.	not available	044949016	GENETIC SPA	IT
LIAFLOX 3 mg/ml collirio, soluzione	not available	044950020	GENETIC SPA	IT
LIAFLOX 3 mg/ml collirio, soluzione	not available	044950018	GENETIC SPA	IT
EXOCIN 3mg/g unguento oftalmico	not available	027234020	ABBVIE S.R.L.	IT
Gramigut 3 mg/ml collirio, soluzione in contenitore monodose	AT/H/0433/001	050683010	OMNIVISION ITALIA S.R.L.	IT
Gramigut 3 mg/ml collirio, soluzione in	AT/H/0433/001	050683022	OMNIVISION ITALIA S.R.L.	IT

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contenitore monodose				
FLOXIGEN 3 mg/ml collirio, soluzione - 1 flacone	not available	043627025	FARMIGEA SPA	IT
FLOXIGEN 3 mg/ml collirio, soluzione	not available	043627013	FARMIGEA SPA	IT
UNIFLOX 3 mg/ml akių lašai (tirpalas)	not available	LT/1/09/1614/001	UNIMED PHARMA SPOL.S R.O.	LT
UNIFLOX 3 mg/ml akių lašai (tirpalas)	not available	LT/1/09/1614/002	UNIMED PHARMA SPOL.S R.O.	LT
Ofloxa-Vision Kombi-Packung 3 mg/ml Augentropfen, Lösung und 3 mg/g Augensalbe	DE/H/6413/001	2021040062	OMNIVISION GMBH	LU
VisioFlox 3 mg/g Augensalbe	AT/H/0767/001	2019070207	OMNIVISION GMBH	LU
UNIFLOX® 0,3 % acu pilieni, šķīdums	not available	05-0579	UNIMED PHARMA SPOL.S R.O.	LV
Otiflox Unit Dose 1,5 mg/0,5 ml oordruppels, oplossing	NL/H/2980/001	RVG 113973	PHARMA STULLN GMBH	NL
Ofloxacin-POS 3 mg/ml, oogdruppels, oplossing	NL/H/2482/001	RVG 110894	URSAPHARM BENELUX B.V.	NL
Ofloxacin Stulln 3 mg/ml oogdruppels, oplossing	NL/H/2394/001	RVG 109913	PHARMA STULLN GMBH	NL
Trafloxal oogzalf, oogzalf 3 mg/g.	not available	RVG 13511	BAUSCH + LOMB IRELAND LIMITED	NL
Ofloxacin Devatis 3 mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik	NL/H/2858/001	RVG 113360	DEVATIS GMBH	NL
Ofloxacin Devatis 3 mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik	NL/H/2858/001	RVG 113360	DEVATIS GMBH	NL
Ofloxacin Devatis 3	NL/H/2858/001	RVG 113360	DEVATIS GMBH	NL

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mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik				
Ofloxacin Devatis 3 mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik	NL/H/2858/001	RVG 113360	DEVATIS GMBH	NL
Ofloxacin Devatis 3 mg/ml, oogdruppels, oplossing, Verpakking voor éénmalig gebruik	NL/H/2858/001	RVG 113360	DEVATIS GMBH	NL
Ofloxacin Eberth 3 mg/ml oogdruppels, oplossing	NL/H/2392/001	RVG 109911	DR. FRIEDRICH EBERTH ARZNEIMITTEL GMBH	NL
Ofloxacin Stulln Unit Dose 3 mg/ml oogdruppels, oplossing	NL/H/2393/001	RVG 109912	PHARMA STULLN GMBH	NL
Trafloxal oogdruppels, oogdruppels 3 mg/ml	not available	RVG 13510	BAUSCH + LOMB IRELAND LIMITED	NL
Trafloxal E.D.O. 3 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	not available	RVG 29805	BAUSCH + LOMB IRELAND LIMITED	NL
Ofloxacin-POS, 3 mg/ml, krople do oczu, roztwór	NL/H/2482/001/DC	20751	URSAPHARM POLAND SP. Z. O.O.	PL
Ofloxamed, 3 mg/ml, krople do oczu, roztwór	SE/H/1285/001	22005	SUN-FARM SP. Z.O.O.	PL
Ofloxamed, 3 mg/ml, krople do oczu, roztwór	SE/H/1285/001	22005	SUN-FARM SP. Z.O.O.	PL
Floxal, 3 mg/ml, krople do oczu, roztwór	not available	4116	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	PL
VisioFlox, 3 mg/g, maść do oczu	AT/H/0767/001	25519	PHARM SUPPLY SP. Z O.O.	PL
Floxal, 3 mg/g, maść do oczu	not available	4115	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	PL
Oflodine, 3 mg/ml, krople do oczu, roztwór	NL/H/2392/001	20810	ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.	PL
FARMIFLOX 3 mg/ml	PT/H/1425/001	5692066	FARMIGEA SPA	PT

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colírio, solução				
FARMIFLOX 3 mg/ml colírio, solução em recipiente unidose	PT/H/1425/002	5692157	FARMIGEA SPA	PT
Exocin 3 mg/ml colírio, solução	not available	2427482	ABBVIE, LDA.	PT
Audret, 3 mg/ml, colírio, solução.	PT/H/1471/001	5697255	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 3 mg/ml, colírio, solução.	PT/H/1471/001	5697263	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 3 mg/ml, colírio, solução.	PT/H/1471/001	5616271	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5424239	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5424247	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5424254	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5424262	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5424270	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol 3 mg/ml gel oftálmico	not available	5204441	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret 3 mg/ml gel oftálmico	not available	5656152	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 3 mg/ml, colírio, solução	not available	2396497	LABORATÓRIO EDOL - PRODUTOS	PT

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			FARMACÊUTICOS, S.A.	
Floxedol, 3 mg/ml, colírio, solução	not available	5697305	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 3 mg/ml, colírio, solução	not available	5697313	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Ottoflox 3 mg/ml gotas auriculares, solução	not available	5211602	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxad 3 mg/ml picături oftalmice, soluție	not available	8455/2015/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	RO
UNIFLOX 3 mg/ml picături oftalmice și auriculare, soluție	not available	14481/2022/01	UNIMED PHARMA SPOL.S R.O.	RO
UNIFLOX 3 mg/ml picături oftalmice și auriculare, soluție	not available	14481/2022/02	UNIMED PHARMA SPOL.S R.O.	RO
FLOXAL 3 mg/g unguent oftalmic	not available	8456/2015/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	RO
Ofloxacin mibe 3 mg/ml ögondropper, lösning.	SE/H/1285/001	49243	MIBE GMBH ARZNEIMITTEL	SE
Ofloxacin mibe 3 mg/ml ögondropper, lösning.	SE/H/1285/001	49243	MIBE GMBH ARZNEIMITTEL	SE
UNIFLOX 0,3 % očné/ušné roztokové kvapky	not available	64/0013/02-S	UNIMED PHARMA SPOL.S R.O.	SK
EXOCIN® 3 mg/ml Eye Drops, Solution.	not available	PL 41042/0064	ABBVIE LTD (UK)	XI