



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 November 2018
EMA/857715/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ofloxacin (topical use)

Procedure no.: PSUSA/00002204/201804



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
Ofloxacin ELC 3 mg/ml ocni kapky, roztok v jednodávkovém obalu	PT/H/1425/01-02/DC	64/636/15-C	ELC GROUP S.R.O.	CZ
Ofloxacin ELC 3mg/ml Augentropfen, Losung im Einzeldosisbehältnis	PT/H/1425/01-02/DC	94788.00.00	ELC GROUP S.R.O.	DE
OFLOXACIN ELC 3 mg/ml oldatos szemcsepp egyadagos tartályban	PT/H/1425/02/DC	OGYI-T-23124/02	ELC GROUP S.R.O.	HU
Ofloxa-Vision sine 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	AT/H/0433/001/DC	1-31917	OMNIVISION GMBH	AT
Ofloxa-Vision sine 3 mg/ml Augentropfen, Lösung im Einzeldosisbehältnis	AT/H/0433/001/DC	86236.00.00	OMNIVISION GMBH	DE
FLOXAL 3 mg/g unguent oftalmic	not available	8456/2015/01	DR. GERHARD MANN CHEM.- PHARM. FABRIK GMBH	RO
FLOXIGEN 3 mg/ml collirio, soluzione	not available	043627013	FARMIGEA SPA	IT
FLOXIGEN 3 mg/ml collirio, soluzione	not available	043627025	FARMIGEA SPA	IT
QUINOFREE 1,5 mg/ 0,5 ml, collyre en récipient unidose	not available	34009 499 526 7 0	LABORATOIRES THEA	FR

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
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
Floxal 3 mg/g szemkenőcs	not available	OGYI-T-4929/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	HU
Ofloxacin-Ophtal® sine 3 mg/ml Augentropfen	not available	45031.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ofloxacin Stulln® UD 3 mg/1 ml Augentropfen	not available	79808.00.00	PHARMA STULLN GMBH	DE
Ofloxacin-ratiopharm 3 mg/ml Augentropfen	NL/H/2394/001	85248.00.00	RATIOPHARM GMBH	DE
Ofloxacin Stulln 3 mg/ml oogdruppels, oplossing	NL/H/2394/001	RVG 109913	PHARMA STULLN GMBH	NL
Trafloxal E.D.O. 3 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	not available	RVG 29805	BAUSCH & LOMB PHARMA	NL
Ofloxacin-Ophtal 3 mg/g Augensalbe	not available	89480.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE

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
Floxxal 3 mg/ml oldatos szemcsepp	not available	OGYI-T-4928/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	HU
EUKINOFT 3 mg/ml collirio, soluzione	not available	039435019	VISUFARMA SPA	IT
OXATREX, Οφθαλμικές σταγόνες, διάλυμα μιας δόσης 1,5mg/0,5ml (0,3%W/V ή 3mg/1ML)	not available	46171/14/07-01-2015	ZWITTER PHARMACEUTICALS ΕΠΕ	GR
Trafloxal 3 mg/ml collyre en solution	not available	BE153054	BAUSCH & LOMB PHARMA	BE
Trafloxal 3 mg/ml oogdruppels, oplossing	not available	BE153054	BAUSCH & LOMB PHARMA	BE
Floxxal® - Augentropfen	not available	1-19054	BAUSCH & LOMB GMBH	AT
Floxxal 3 mg/ml picături oftalmice, soluție	not available	8455/2015/01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	RO
Floxxal, 3 mg/ml, krople do oczu, roztwór	not available	4116	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	PL
OFLOXAVIS 3 mg/ml colirio en solución	NL/H/2392/001	77631	PHARMA STULLN GMBH	ES

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Ofloxa-Vision 3mg/ml Augentropfen, Lösung	NL/H/2392/001	85247.00.00	OMNIVISION GMBH	DE
Oflodinex, 3 mg/ml, krople do oczu, roztwór	NL/H/2392/001	20810	ZAKLADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Ofloxacin Eberth 3 mg/ml oogdruppels, oplossing	NL/H/2392/001	RVG 109911	DR. FRIEDRICH EBERTH ARZNEIMITTEL GMBH	NL
Ofloxacin Stulln 3 mg/ml Augentropfen	NL/H/2392/001	1-31663	PHARMA STULLN GMBH	AT
Ofloxacin ELC 3 mg/ml ocni kapky, roztok	PT/H/1425/01-02/DC	64/635/15-C	ELC GROUP S.R.O.	CZ
Ofloxacin ELC 3 mg/ml Augentropfen, Losung	PT/H/1425/01-02/DC	94789.00.00	ELC GROUP S.R.O.	DE
OFLOXACINA ELC GROUP 3 mg/ml colirio, solucao	PT/H/1425/01/DC	5692066	ELC GROUP S.R.O.	PT
OFLOXACIN ELC 3 mg/ml oldatos szemcsepp	PT/H/1425/002	OGYI-T-23124/01	ELC GROUP S.R.O.	HU
Audret 3 mg/ml gel oftálmico	not available	5656152	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT

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
MONOFLOXOFTA® 0,3 % collirio, soluzione	not available	039901018	SOOFT ITALIA S.P.A.	IT
Floxal® 3 mg/g Augensalbe	not available	15583.00.01	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
EXOCIN® 3 mg/ml, ögondroppar, lösning	not available	11691	ALLERGAN PHARMACEUTICALS IRELAND	FI
EXOCIN®	not available	39476/30-11-2012	ALLERGAN PHARMACEUTICALS IRELAND	GR
Exocin 3 mg/ml, silmätipat, liuos	not available	11691	ALLERGAN PHARMACEUTICALS IRELAND	FI
EXOCINE® 0,3 POUR CENT, collyre	not available	34009 331 708 0 6	ALLERGAN FRANCE	FR
EXOCIN (Ofloxacin) 0.3% w/v Eye Drops Solution	not available	PA 148/49/1	ALLERGAN PHARMACEUTICALS IRELAND	IE
EXOCIN 3 mg/ml collirio, soluzione	not available	027234032	ALLERGAN S.P.A.	IT
EXOCIN 3mg/g unguento oftalmico	not available	027234020	ALLERGAN S.P.A.	IT

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
Exocin 3 mg/ml colírio, solução	not available	2427482	ALLERGAN, S.A.U.	PT
Exocin 3 mg/ml colírio, solução	not available	2427581	ALLERGAN, S.A.	PT
EXOCIN 3 mg/ml colirio en solución	not available	62.560	ALLERGAN, S.A.U.	ES
EXOCIN® 3 mg/ml Eye Drops, Solution	not available	PL 00426/0070	ALLERGAN LTD	UK
Флоксал 3 mg/g маз за очи	not available	20070008	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
Floxal 3 mg/ml oční kapky, roztok	not available	64/367/00-C	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	CZ
Floxal® 3 mg/ml Augentropfen	not available	15583.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Ottoflox 3 mg/ml gotas auriculares, solução	not available	5211602	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

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
Floxedol, 1,5 mg/0,5 ml, col 11 rio, solu 777Jo em recipiente unidose	not available	5424247	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, col 11 rio, solu 777Jo em recipiente unidose	not available	5424254	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, col 11 rio, solu 777Jo em recipiente unidose	not available	5424262	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 1,5 mg/0,5 ml, col 11 rio, solu 777Jo em recipiente unidose	not available	5424270	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 3 mg/ml, col 11 rio, solu 777Jo	not available	2396497	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol 3 mg/ml gel oftálmico	not available	5204441	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 3 mg/ml, col 11 rio, solu 777Jo	not available	5697305	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Floxedol, 3 mg/ml, col 11 rio, solu 777Jo	not available	5697313	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Ofloxacin-POS 3 mg/ml, eye drops, solution	NL/H/2482/001/E/001	MA063/00901	URSAPHARM ARZNEIMITTEL GMBH	MT

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
VisuAb, 3 mg/ml collirio, soluzione	NL/H/2482/001	044623015	VISUFARMA SPA	IT
Ofloxacino POS 3 mg/ml colirio en solución	NL/H/2482/001	81022	BRILL PHARMA, S.L.	ES
Ofloxacine-POS 3 mg/ml, oogdruppels, oplossing	NL/H/2482/001/DC	RVG 110894	URSAPHARM BENELUX B.V.	NL
Ofloxacin-POS 3 mg/ml Augentropfen	NL/H/2482/001/DC	86497.00.00	URSAPHARM ARZNEIMITTEL GMBH	DE
Ofloxacin-POS 3 mg/ml oční kapky, roztok	NL/H/2482/001/DC	64/686/12-C	URSAPHARM SPOL. S.R.O.	CZ
Ofloxacin-POS, 3 mg/ml, krople do oczu, roztwór	NL/H/2482/001/DC	20751	URSAPHARM POLAND SP. Z. O.O.	PL
Floxal® EDO®	not available	35778.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE
Floxal 3 mg/g oční mast	not available	64/368/00-C	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	CZ
Ofloxamed(R) 3 mg/ml Augentropfen	SE/H/1285/01/DC	89384.00.00	MIBE GMBH ARZNEIMITTEL	DE

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Ofloxacin mibe, 3 mg/ml ögondroppar, lösning	SE/H/1285/01/DC	49243	MIBE GMBH ARZNEIMITTEL	SE
Ofloxamed(R) 3mg/ml krople do oczu	SE/H/1285/01/DC	22005	SUN-FARM SP. Z.O.O.	PL
Ofloxacin-ratiopharm 3 mg/ml Augentropfen im Einzeldosisbehältnis	NL/H/2393/001	85249.00.00	RATIOPHARM GMBH	DE
Ofloxacin Stulln 3 mg/ml Augentropfen im Einzeldosisbehältnis	NL/H/2393/001	1-31664	PHARMA STULLN GMBH	AT
Ofloxacin Stulln Unit Dose 3 mg/ml oogdruppels, oplossing	NL/H/2393/001	RVG 109912	PHARMA STULLN GMBH	NL
Ofloxacin Bipharm 3 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	PT/H/1266/001	RVG 115764	BIPHARMA B.V.	NL
Ofloxacin Bipharm 3 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	PT/H/1266/001	BE487733	BIPHARMA B.V.	BE
Ofloxacin Bipharm 3 mg/ml, collyre en solution, récipient unidose	PT/H/1266/001	BE487733	BIPHARMA B.V.	BE

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
Ofloxacin Bipharma 3 mg/ml Augentropfen, Lösung in einem Einzeldosisbehältnis	PT/H/1266/001	BE487733	BIPHARMA B.V.	BE
Ofloxacina Bipharma 1.5mg/0.5ml, Colírio, solução em recipiente unidose	PT/H/1266/001	PT/H/1266/001	BIPHARMA B.V.	PT
Floxal Augensalbe	not available	1-23679	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	AT
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 Augentropfen im Einzeldosisbehältnis	NL/H/2858/001	89755.00.00	DEVATIS GMBH	DE
Trafloxal oogdruppels, oogdruppels 3 mg/ml	not available	RVG 13510	BAUSCH & LOMB PHARMA	NL
EUKINOFT 3 mg/ml collirio, soluzione	not available	039435021	VISUFARMA SPA	IT
OFLOCET 1,5 mg/0,5 ml, solution auriculaire en récipient unidose	not available	339 863-5	SANOFI-AVENTIS FRANCE	FR

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
Oflozet®	not available	MA082/01801	SANOFI MALTA LTD	MT
Multifloxafta 3 mg/ml collirio, soluție	PT/H/1471/001	045392014	SOOFT ITALIA S.P.A.	IT
Multifloxafta 3 mg/ml collirio, soluție	PT/H/1471/001	045392026	SOOFT ITALIA S.P.A.	IT
Multifloxafta 3 mg/ml collirio, soluție	PT/H/1471/001	045392038	SOOFT ITALIA S.P.A.	IT
Romacin 3 mg/ml picături oftalmice, soluție	PT/H/1471/001	10248/2017/01	SOOFT ITALIA S.P.A.	RO
Romacin 3 mg/ml picături oftalmice, soluție	PT/H/1471/001	10248/2017/02	SOOFT ITALIA S.P.A.	RO
Romacin 3 mg/ml picături oftalmice, soluție	PT/H/1471/001	10248/2017/03	SOOFT ITALIA S.P.A.	RO
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

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
Audret, 3 mg/ml, colírio, solução	PT/H/1471/001	5616271	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5616305	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5616313	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5616321	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5616339	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Audret, 1,5 mg/0,5 ml, colírio, solução em recipiente unidose	not available	5616347	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Флоксал 3 mg/ml капли за очи, раствор	not available	20060871	PHARMASWISS ČESKÁ REPUBLIKA S.R.O.	BG
Otiflox 1,5 mg/0,5 ml Ohrentropfen im Einzeldosisbehältnis	NL/H/2980/001/DC	135917	PHARMA STULLN GMBH	AT
Otiflox Unit Dose 1,5 mg/0,5 ml oordruppels, oplossing	NL/H/2980/001	RVG 113973	PHARMA STULLN GMBH	NL

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Ofloxacin Stulln 3 mg/ml Augentropfen im Einzeldosisbehältnis	NL/H/2393/001	1-31664	PHARMA STULLN GMBH	AT
Trafloxal 3 mg/g pommade ophtalmique	not available	BE156825	BAUSCH & LOMB PHARMA	BE
Trafloxal 3 mg/g oogzalf	not available	BE156825	BAUSCH & LOMB PHARMA	BE
Ofloxacin-POS 3 mg/ml, eye drops, solution	NL/H/2482/001/E/001	MA063/00901	URSAPHARM ARZNEIMITTEL GMBH	MT
VisuAb, 3 mg/ml collirio, soluzione	NL/H/2482/001	044623015	VISUFARMA SPA	IT
Ofloxacino POS 3 mg/ml colirio en solución	NL/H/2482/001	81022	BRILL PHARMA, S.L.	ES
Ofloxacin-POS 3 mg/ml, oogdruppels, oplossing	NL/H/2482/001/DC	RVG 110894	URSAPHARM BENELUX B.V.	NL
Ofloxacin-POS 3 mg/ml Augentropfen	NL/H/2482/001/DC	86497.00.00	URSAPHARM ARZNEIMITTEL GMBH	DE
Ofloxacin-POS 3 mg/ml oční kapky, roztok	NL/H/2482/001/DC	64/686/12-C	URSAPHARM SPOL. S.R.O.	CZ

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Ofloxacin-POS, 3 mg/ml, krople do oczu, roztwór	NL/H/2482/001/DC	20751	URSAPHARM POLAND SP. Z. O.O.	PL
Ofloxacin Bipharma 3 mg/ml oogdruppels, oplossing	PT/H/1267/001	RVG 115765	BIPHARMA B.V.	NL
Ofloxacin Bipharma 3 mg/ml oogdruppels, oplossing	PT/H/1267/001	BE485946	BIPHARMA B.V.	BE
Ofloxacin Bipharma 3 mg/ml, collyre en solution	PT/H/1267/001	BE485946	BIPHARMA B.V.	BE
Ofloxacin Bipharma 3 mg/ml Augentropfen, Lösung	PT/H/1267/001	BE485946	BIPHARMA B.V.	BE
Ofloxacina Bipharma, 3 mg/ml, Colírio, solução	PT/H/1267/001	PT/H/1267/001	BIPHARMA B.V.	PT
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
MONOOX 1,5 mg/0,5 ml, collyre en solution en récipient unidose	not available	34009 583 313 0 5	HORUS PHARMA	FR

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MONOOX 1,5 mg/0,5 ml, collyre en solution en récipient unidose	not available	34009 583 312 4 4	HORUS PHARMA	FR
OFLOXACINE BIOGARAN 1,5 mg/0,5 ml, solution pour instillation auriculaire en récipient unidose	not available	3400949642557	BIOGARAN	FR
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/DC	137160	OMNIVISION GMBH	AT
Ofloxa-Vision 3 mg/g Augensalbe	AT/H/0544/001/DC	92145.00.00	OMNIVISION GMBH	DE
Trafloxal oogzalf, oogzalf 3 mg/g	not available	RVG 13511	BAUSCH & LOMB PHARMA	NL
Floxal, 3 mg/g, maść do oczu	not available	4115	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	PL
Oflodinex, 3 mg/ml, krople do oczu, roztwór	NL/H/2392/001	20810	ZAKŁADY FARMACEUTYCZNE "POLPHARMA" SPOLKA AKCYJNA	PL
Trafloxal EDO 3 mg/ml collyre en solution en récipient unidose	not available	BE227141	BAUSCH & LOMB PHARMA	BE

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Trafloxal EDO 3 mg/ml oogdruppels, oplossing in verpakking voor éénmalig gebruik	not available	BE227141	BAUSCH & LOMB PHARMA	BE
Ofloxacin-Ophtal® 3 mg/ml Augentropfen	not available	89479.00.00	DR. GERHARD MANN CHEM.-PHARM. FABRIK GMBH	DE