



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2015
EMA/62578/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ofloxacin (topical use)

Procedure no.: PSUSA/00002204/201504



Product Name	MRP DCP Authorisation Number	National Authorisation Number	MAH Name	Authorisation country
Floxal		1-19054	Bausch & Lomb Gmbh	AT
Ofloxamed	SE/H/1285/01/DC	135742	Dermapharm Gmbh	AT
Ofloxa-Vision Sine	AT/H/0433/001/DC	1-31917	Omnivision Gmbh	AT
Ofloxacin Stulln	NL/H/2392/001	1-31663	Pharma Stulln Gmbh	AT
Ofloxacin Stulln	NL/H/2393/001	1-31664	Pharma Stulln Gmbh	AT
Otiflox	NL/H/2980/001/DC	135917	Pharma Stulln Gmbh	AT
Trafloxal		BE153054	Bausch & Lomb Pharma	BE
Trafloxal		BE156825	Bausch & Lomb Pharma	BE
Trafloxal Edo		BE227141	Bausch & Lomb Pharma	BE
флоксал		20060871	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	BG
флоксал		20070008	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	BG
Uniflox		20020082	Unimed Pharma Spol.S R.O.	BG
Floxal		64/367/00-C	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	CZ
Floxal		64/368/00-C	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	CZ
Ofloxacin		64/324/06-C	Unimed Pharma Spol.S R.O.	CZ
Exocin		14741	Allergan Pharmaceuticals Ireland	DA
Exocin		11691	Allergan Pharmaceuticals Ireland	FI
Exocine		34009 331 708 0 6	Allergan France	FR
Ofloxacin Biogaran		37221	Biogaran	FR

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Monoox		266 191-2 ou 34009 266 191 2 1 266 192-9 ou 34009 266 192 9 9 583 312-4 ou 34009 583 312 4 4 583 313-0 ou 34009 583 313 0 5	Horus Pharma	FR
Quinofree		34009 499 526 7 0 34009 579 206 9 2 34009 579 207 5 3	Laboratoires Thea	FR
Oflocet		NL 20914	Sanofi-Aventis France	FR
Ofloxacin Eberth	NL/H/2392/001	85247.00.00	Dr. Friedrich Eberth Arzneimittel Gmbh	DE
Floxal		15583.00.00	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	DE
Floxal		15583.00.01	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	DE
Floxal		35778.00.00	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	DE
Floxal		89480.00.00	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	DE
Ofloxacin-Ophtal		45031.00.00	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	DE
Ofloxacin-Ophtal		89479.00.00	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	DE
Ofloxamed	SE/H/1285/01/DC	89384.00.00	Mibe Gmbh Arzneimittel	DE
Ofloxa-Vision Sine	AT/H/0433/001/DC	86236.00.00	Omnivision Gmbh	DE
Ofloxacin Stulln		79808.00.00	Pharma Stulln Gmbh	DE
Ofloxacin Stulln		83541.00.00	Pharma Stulln Gmbh	DE
Ofloxacin Ratiopharm	NL/H/2393/001/DC	85249.00.00	ratiopharm GmbH	DE
Ofloxacin Ratiopharm	NL/H/2394/001/DC	85248.00.00	ratiopharm GmbH	DE

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Ofloxacin Regiomedica	NL/H/2858/001/DC	89755.00.00	Regiomedica Gmbh	DE
Ofloxacin-Pos	NL/H/2482/001/DC	86497.00.00	Ursapharm Arzneimittel Gmbh	DE
Exocin		39476/30-11-2012	Allergan Pharmaceuticals Ireland	EL
Oxatrex		46171/14/07-01-2015	Zwitter Pharmaceuticals επε	EL
Floxal		OGYI-T-4928/01	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	HU
Floxal		OGYI-T-4929/01	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	HU
Ofloxacin		OGYI-T-22718/01 OGYI-T-22718/02	Unimed Pharma Spol.S R.O.	HU
Exocin		PA 148/49/1	Allergan Pharmaceuticals Ireland	IE
Exocin		027234020	Allergan S.P.A.	IT
Exocin		027234032	Allergan S.P.A.	IT
Eukinoft		039435019 039435021	Nicox Farma S.R.L.	IT
Uniflox		05-0579	Unimed Pharma Spol.S R.O.	LV
Uniflox		LT/1/09/1614/001 LT/1/09/1614/002	Unimed Pharma Spol.S R.O.	LT
Oflocet		082/01801	Sanofi Malta Ltd	MT
Trafloxal		RVG 13510	Bausch & Lomb Pharma	NL
Trafloxal		RVG 13511	Bausch & Lomb Pharma	NL
Trafloxal E.D.O.		RVG 29805	Bausch & Lomb Pharma	NL
Ofloxacin Eberth	NL/H/2392/001	RVG 109911	Dr. Friedrich Eberth Arzneimittel Gmbh	NL
Ofloxacin Stulln	NL/H/2394/001	RVG 109913	Pharma Stulln Gmbh	NL
Ofloxacin Unit Dose Stulln	NL/H/2393/001	RVG 109912	Pharma Stulln Gmbh	NL
Otiflox	NL/H/2980/001/DC	RVG113973	Pharma Stulln Gmbh	NL

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Ofloxacin Regiomedica	NL/H/2858/001/DC	RVG 113360	Regiomedica Gmbh	NL
Ofloxacin Sandoz	RVG 113632	RVG 113632	Sandoz B.V.	NL
Floxal		4115	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	PL
Floxal		4116	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	PL
Ofloxamed	SE/H/1285/01/DC	22005	Sun-Farm Sp. Z.O.O. (Kolbiel)	PL
Floximox	NL-H-2394-001	20721	Teva Pharmaceuticals Polska Sp. Z O.O.	PL
Oflodinex	NL/H/2392/001	20810	Zakłady Farmaceutyczne "polpharma" Spółka Akcyjna	PL
Exocin		2427482 2427581	Allergan, S.A.U.	PT
Audret		5616271	Gide Farma - Produtos Farmacêuticos, Lda	PT
Audret		5616305 5616313 5616321 5616339 5616347	Gide Farma - Produtos Farmacêuticos, Lda	PT
Floxedol		2396497	Laboratório Edol - Produtos Farmacêuticos, S.A.	PT
Floxedol		5204441	Laboratório Edol - Produtos Farmacêuticos, S.A.	PT
Floxedol		5424239 5424247 5424254 5424262 5424270	Laboratório Edol - Produtos Farmacêuticos, S.A.	PT
Ottoflox		5211602	Laboratório Edol - Produtos Farmacêuticos, S.A.	PT
Floxal		5039/2004/01	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	RO

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Floxal		5040/2004/01	Dr. Gerhard Mann Chem.-Pharm. Fabrik Gmbh	RO
Uniflox		5061/2004/01 5061/2004/02	Unimed Pharma Spol.S R.O.	RO
Uniflox		64/0013/02-S	Unimed Pharma Spol.S R.O.	SK
Exocin		62.560	Allergan S.A.	ES
Ofloxacin Eberth	NL/H/2392/001	77631	Dr. Friedrich Eberth Arzneimittel Gmbh	ES
Ofloxacin Mibe	SE/H/1285/01/DC	49243	Mibe Gmbh Arzneimittel	SE
Exocin		PL 00426/0070	Allergan Ltd	UK