



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2015
EMA/85786/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ofloxacin (systemic use)

Procedure no.: PSUSA/00002203/201504



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
Bioquil		4653796 \$ 4817995 \$ 4818092 \$ 4818191 \$ 9752204	Laboratórios Atral, S.A.	Portugal
Bioquil		4653796;9752204 \$ 4817995;4818092; 4818191	Laboratórios Atral, S.A.	Portugal
Cilox		14717 \$ 16037	Remedica Ltd	Cyprus
Gyroflox	UK-H-0510-001-002-MR	54321.00.00 \$ 54321.01.00	Teva Gmbh	Germany
Medofloxine		02-0290	Medochemie Ltd.	Latvia
Medofloxine		13357	Medochemie Ltd.	Cyprus
Medofloxine		42/0324/03-S	Medochemie Ltd.	Slovakia
Medofloxine 200 mg		485905	Medochemie Ltd.	Estonia
Oflocet		4669586 \$ 8637835	Sanofi-Aventis Produtos Farmaceuticos S.A.	Portugal
Oflogen		OGYI-T-9291/01 \$ OGYI-T-9291/02 \$ OGYI-T-9291/03 \$ OGYI-T-9291/04 \$ OGYI-T-9291/05	Generics [uk] Limited	Hungary
Oflogen		OGYI-T-9291/06 \$ OGYI-T-9291/07 \$ OGYI-T-9291/08 \$ OGYI-T-9291/09	Generics [uk] Limited	Hungary
Oflohexal		45342.00.00	Hexal Ag	Germany
Oflohexal		45342.01.00 \$ 45342.02.00	Hexal Ag	Germany
Oflox		68562.00.00	Sandoz Pharmaceuticals Gmbh	Germany
Oflox	DE/H/0312/001/MR \$ DE/H/0312/002/MR	46978.00.00 \$ 46978.01.00 \$ 46978.02.00	Basics Gmbh	Germany
Ofloxacin		PL 00289/0353 \$ PL 00289/0354	Teva Uk Limited Brampton Road, Hampden Park	United Kingdom
Ofloxacin	UK-H-0510-001-002-MR	PL 14776/0054 \$ PL 14776/0055	Teva Pharma B.V. Computerweg 10	United Kingdom
Ofloxacin 1 A Pharma		45852.00.00	1 A Pharma Gmbh	Germany
Ofloxacin 1 A Pharma		45852.01.00	1 A Pharma Gmbh	Germany

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Ofloxacin 1 A Pharma		45852.02.00	1 A Pharma Gmbh	Germany
Ofloxacin Abz		46990.01.00	Abz-Pharma Gmbh, Graf-Arco-Str. 3	Germany
Ofloxacin Al		46999.00.00	Aliud Pharma Gmbh	Germany
Ofloxacin Al		46999.01.00	Aliud Pharma Gmbh	Germany
Ofloxacin Al		46999.02.00	Aliud Pharma Gmbh	Germany
Ofloxacin Bristol Laboratories		PL 17907/0024	Bristol Laboratories Ltd (Berkhamsted)	United Kingdom
Ofloxacin Bristol Laboratories		PL 17907/0025	Bristol Laboratories Ltd (Berkhamsted)	United Kingdom
Ofloxacin Generics Uk	NL/H/0979/001 \$ NL/H/0979/002	PL 04569/0549 \$ PL 04569/0550	Mylan, Lda	United Kingdom
Ofloxacin Ratiopharm		46984.00.00	Ratiopharm Gmbh	Germany
Ofloxacin Ratiopharm		NL27776	Ratiopharm Gmbh	France
Ofloxacin Ratiopharm	DE-H-0317-001-002	1-24394 \$ 1-24395	Ratiopharm Arzneimittel Vertriebs-Gmbh	Austria
Ofloxacin Ratiopharm	DE-H-0317-001-002	46984.01.00 \$ 46984.02.00	Ratiopharm Gmbh	Germany
Ofloxacin Stada		54542.01.00 \$ 54542.02.00	Stadapharm Gmbh	Germany
Ofloxacin Stada	DE/H/0360/001	1-24854	Stada Arzneimittel Gmbh	Austria
Ofloxacin Stada	DE/H/0360/001 \$ DE/H/0360/002	46993.01.00 \$ 46993.02.00	Stadapharm Gmbh	Germany
Ofloxacin Stada	DE/H/0360/002	1-24855	Stada Arzneimittel Gmbh	Austria
Ofloxacin Uro Stada		46993.00.00	Stadapharm Gmbh	Germany

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 Mylan	NL/H/0979/001	4167185 \$ 4167284 \$ 4167383 \$ 4167482 \$ 4167581 \$ 4167680 \$ 4167789 \$ 4167888 \$ 4167987 \$ 4168084 \$ 4168183 \$ 4168282 \$ 4168381 \$ 4168480 \$ 4168589 \$ 4168688 \$ 4168787 \$ 4168886 \$ 4168985 \$ 4169082 \$ 4169181 \$ 4169280 \$ 4169389 \$ 4169488 \$ 4169587 \$ 4169686 \$ 4351086 \$ 4351185	Mylan, Lda	Portugal
Ofloxacin	UK-H-0510-001-002-MR	BE 239163 \$ BE 239172	Teva Pharma Belgium N.V.	Belgium
Ofloxacin	UK-H-0510-001-002-MR	RVG 27571 \$ RVG 27572	Pharmachemie B.V.	Netherlands
Ofloxacin Arrow		28505	Arrow Generiques	France
Ofloxacin Centrafarm		RVG 28727	Centrafarm B.V.	Netherlands
Ofloxacin Centrafarm		RVG 28728	Centrafarm B.V.	Netherlands
Ofloxacin Cristers		34009 376 734 0 2 \$ 34009 569 883 8 9	Cristers	France
Ofloxacin Eg	DE/H/0360/001	BE250975	Eurogenerics Sa	Belgium
Ofloxacin Eg	DE/H/0360/001 \$ DE/H/0360/002	0019/04/05/0016 \$ 0019/04/05/0017	Eurogenerics Sa	Luxembourg
Ofloxacin Eurogenerics	DE/H/0360/002	BE250993	Eurogenerics Sa	Belgium
Ofloxacin Maco Pharma		34009 566 774 3 6	Maco Pharma	France
Ofloxacin Macopharma		34009 566 776 6 5	Maco Pharma	France
Ofloxacin Mylan		NL 27 098	Mylan S.A.S	France
Ofloxacin Mylan		NL 30 396	Mylan S.A.S	France
Ofloxacin Mylan	NL/H/0979/001 \$ NL/H/0979/002	0007/02/10/0037 \$ 0007/02/10/0038	Mylan Bvba/Sprl	Luxembourg
Ofloxacin Mylan	NL/H/0979/001 \$ NL/H/0979/002	BE240125 \$ BE240134 \$ BE240143 \$ BE240152	Mylan Bvba/Sprl	Belgium
Ofloxacin Mylan	NL/H/0979/001 \$ NL/H/0979/002	RVG 27753 \$ RVG 27754	Mylan, Lda	Netherlands

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Ofloxacin Mylan Pharma		NL 27 256	Mylan S.A.S	France
Ofloxacin Phr Lab		NL 32877	Biogaran	France
Ofloxacin Ranbaxy		NL 31020	Ranbaxy Pharmacie Generiques	France
Ofloxacin Sandoz		1472 PI 2 F3	Sandoz N.V.	Belgium
Ofloxacin Sandoz		364 529-8 \$ 565 546-7 \$ 565 547-3	Sandoz	France
Ofloxacin Sandoz	NOT APPLICABLE	1472 PI 3 F3	Sandoz N.V.	Belgium
Ofloxacin Sandoz	RVG 28950 \$ RVG 28951	RVG 28950 \$ RVG 28951	Sandoz B.V.	Netherlands
Ofloxacin Teva		NL27957	Teva Santé	France
Ofloxacin G.E.S.		67741	G.E.S. Genéricos Españoles Laboratorio, S.A.	Spain
Ofloxacin Ranbaxy	DE/H/0312/001/MR	65.053	Laboratorios Ranbaxy S.L.	Spain
Ofloxacin Laropharm		1116/2008/01	Sc Laropharm Srl	Romania
Ofloxin		14408 \$ 19793	Codal Synto Ltd	Cyprus
Ofloxin 200		403402	Zentiva, K.S.	Estonia
Ofloxin		42/0385/96-S	Zentiva, K.S.	Slovakia
Ofloxin		8297/2006/01	Zentiva, K.S.	Romania
Ofloxin		98-0852	Zentiva, K.S.	Latvia
Ofloxin		9900390	Zentiva, K.S.	Bulgaria

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Ofloxin		LT/1/2000/2357/001 \$ LT/1/2000/2357/002	Zentiva, K.S.	Lithuania
Ofloxin 200		42/846/95-C	Zentiva, K.S.	Czech Republic
Ofloxin Inf		42/382/00-C	Zentiva, K.S.	Czech Republic
Oxacid		17306 \$ 17307	Delorbis Pharmaceuticals Ltd	Cyprus
Surnox		59951	Sanofi-Aventis Sa	Spain
Tabrin		10896	Sanofi-Aventis Cyprus Ltd	Cyprus
Tarivid		070794	Sanofi-Aventis Estonia Oü	Estonia
Tarivid		1-18215 \$ 1-20081	Sanofi-Aventis Gmbh Österreich	Austria
Tarivid		1-19047	Sanofi-Aventis Gmbh Österreich	Austria
Tarivid		24720.00.01 \$ 26203.00.00	Sanofi-Aventis Deutschland Gmbh	Germany
Tarivid		24720.01.00	Sanofi-Aventis Deutschland Gmbh	Germany
Tarivid		7581	Sanofi-Aventis Norge As	Norway
Tarivid		7876	Sanofi-Aventis Norge As	Norway
Tarivid		9856	Sanofi Oy	Finland
Tarivid		BE138607	Sanofi Belgium	Belgium
Tarivid		BE156651	Sanofi Belgium	Belgium
Tarivid		BE171351	Sanofi Belgium	Belgium
Tarivid		BE171367	Sanofi Belgium	Belgium

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Tarivid		OGYI-T-3856/01	Gedeon Richter Plc.	Hungary
Tarivid		PA 540/76/2	Sanofi-Aventis Ireland Ltd	Ireland
Tarivid		PA 540/76/3	Sanofi-Aventis Ireland Ltd	Ireland
Tarivid		PL 04425/0216	Aventis Pharma Ltd	United Kingdom
Tarivid		PL 04425/0217	Aventis Pharma Ltd	United Kingdom
Tarivid		R/1112	Sanofi-Aventis Deutschland Gmbh	Poland
Tarivid Iv		PL 04425/0215	Aventis Pharma Ltd	United Kingdom
Taroflox		42/0120/93-S	Sanofi-Aventis Slovakia Sro	Slovakia
Taroflox		42/0120/93-S	Sanofi-Aventis Slovakia Sro	Slovakia
Uro-Tarivid		6125.00.00	Sanofi-Aventis Deutschland Gmbh	Germany
Zanocin		42/0058/02-S	Ranbaxy (Uk) Limited	Slovakia
Zanocin		42/363/98-C	Ranbaxy (Uk) Limited	Czech Republic
Zanocin		6230/2014/01	Ranbaxy (Uk) Limited	Romania
Zanocin		97-0216	Ranbaxy (Uk) Limited	Latvia
Zanocin		LT/1/96/2828/001	Ranbaxy (Uk) Limited	Lithuania
Zanocin		OGYI-T- 6589/01 \$ OGYI-T-6589/02	Ranbaxy (Uk) Limited	Hungary
медофлоксин		20060215	Medochemie Ltd.	Bulgaria

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
OFLOXACINE EVOLUGEN 200 mg, comprimé pelliculé sécable		NL 32876	Evolupharm	France
ofloxacina 2mg/ml		G50/95	Pentafarma - Sociedade Tecnico-Medicinal S.A.	Portugal
GRENIS-OFLO F.C. TABLETS 200MG/TAB		39365	Genepharma S.A.	Greece
Ofloxacin Mylan 200 mg, comprimé pelliculé sécable		NL 27098	Mylan SAS	
OFLOXACINA BACTOFLOX 200 MG COMPRIMIDO REVESTIDO (MG)®		1/12/87	Pentafarma - Sociedade Tecnico-Medicinal S.A.	Portugal
Tarivid 100 mg I.V. oplossing voor infusie		BE171376	Sanofi Belgium	Belgium
Ofloxacin Zentiva 200 mg, comprimé pelliculé sécable		NL30146	Sanofi-Aventis France	France
Monoflocet 200 Mg, comprimé pelliculé		NL 19627	Sanofi-Aventis France	France
Oflocet 200 mg, comprimé pelliculé sécable		NL 14281	Sanofi-Aventis France	France
Oflocet 200 mg/40 ml		NL 15398	Sanofi-Aventis Groupe	France
Tabrin		18381/12034/18-12-1986	SANOFI-AVENTIS AEBE	Greece
Tarivid 200 I.V. solution pour perfusion		0006/03/05/7464	Sanofi-Belgium	Luxembourg
Tarivid 100 I.V. solution pour perfusion		0006/03/05/7463	Sanofi-Belgium	Luxembourg
Tarivid 400 I.V. solution pour perfusion		0006/03/05/7465	Sanofi-Belgium	Luxembourg

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Tarivid 200 mg comprimés pelliculés		0006/03/05/7461	Sanofi-Belgium	Luxembourg
Tarivid 400 mg comprimés pelliculés		0006/03/05/7462	Sanofi-Belgium	Luxembourg
Ofloxacin Biogaran		28172	Biogaran	France