



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2023
EMA/348805/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): ofloxacin (systemic use)

Procedure No. PSUSA/00002203/202304



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 STADA 400 mg Filmtabletten	AT/H/0748/002	1-24855	STADA ARZNEIMITTEL GMBH	AT
Ofloxacin STADA 200 mg Filmtabletten	AT/H/0748/001	1-24854	STADA ARZNEIMITTEL GMBH	AT
Tarivid 200 mg filmomhulde tabletten	not available	BE138607	SANOFI BELGIUM	BE
TARIVID® 200 mg Filmtabletten	not available	BE138607	SANOFI BELGIUM	BE
Tarivid 200 mg comprimés pelliculés	not available	BE138607	SANOFI BELGIUM	BE
Ofloxacin EG 400 mg filmomhulde tabletten	AT/H/0748/002	BE250993	EUROGENERICS N.V./S.A.	BE
Ofloxacin EG 200 mg filmomhulde tabletten	AT/H/0748/001	BE250975	EUROGENERICS N.V./S.A.	BE
Ofloxacin EG 200 mg comprimés pelliculés	AT/H/0748/001	BE250975	EUROGENERICS N.V./S.A.	BE
Ofloxacin EG 400 mg comprimés pelliculés	AT/H/0748/002	BE250993	EUROGENERICS N.V./S.A.	BE
Ofloxacin EG 200 mg Filmtabletten	AT/H/0748/001	BE250975	EUROGENERICS N.V./S.A.	BE
Ofloxacin EG 400 mg Filmtabletten	AT/H/0748/002	BE250993	EUROGENERICS N.V./S.A.	BE
Медофлоксин 200 mg филмирани таблетки	not available	20060215	MEDOCHEMIE LTD.	BG
Cilox 200 mg επικαλυμμένα με υμένιο δισκία	not available	14717	REMEDICA LTD	CY
Cilox 400 mg επικαλυμμένα με υμένιο δισκία	not available	16037	REMEDICA LTD	CY
Ofloxin 200mg film-coated tablets	not available	14408	CODAL SYNTO LTD	CY
Ofloxin 400mg film-coated tablets	not available	19793	CODAL SYNTO LTD	CY
Medofloxine 200 mg	not available	13357	MEDOCHEMIE LTD.	CY

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film-coated tablets				
Ofloxin 200 mg potahované tablety	not available	42/846/95-C	ZENTIVA, K.S.	CZ
OFLOX 100 mg BASICS Filmdabletten	not available	46978.00.00	BASICS GMBH	DE
Ofloxacin AL 200 Ofloxacin 200 mg pro Filmdablette	not available	46999.01.00	ALIUD PHARMA GMBH	DE
Ofloxacin-ratiopharm® 100 mg Filmdabletten	not available	46984.00.00	RATIOPHARM GMBH	DE
OFLOX 200 mg BASICS Filmdabletten	DE/H/0312/001	46978.01.00	BASICS GMBH	DE
OFLOX 400 mg BASICS Filmdabletten	DE/H/0312/002	46978.02.00	BASICS GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Ofloxacin STADA® 200 mg Filmdabletten	not available	54542.01.00	STADAPHARM GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Ofloxacin-ratiopharm® 400 mg Filmdabletten	DE/H/0317/002	46984.02.00	RATIOPHARM GMBH	DE
Ofloxacin-ratiopharm® 200 mg Filmdabletten	DE/H/0317/001	46984.01.00	RATIOPHARM GMBH	DE
Medofloxine 200 mg, õhukese	not available	485905	MEDOCHEMIE LTD.	EE

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polümeerikattega tabletid				
OFLOXIN 200, 200 mg õhukese polümeerikattega tabletid	not available	403402	ZENTIVA, K.S.	EE
Ofloxacin Altan 2 mg/ml solución para perfusión EFG	not available	67.741	ALTAN PHARMACEUTICALS S.A.	ES
OFLOVIR 200 mg comprimidos recubiertos con película	not available	59.653	INDUSTRIA QUÍMICA Y FARMACEÚTICA VIR, S.A.	ES
OFLOXACINE TEVA 200 mg, comprimé pelliculé sécable	not available	NL27957	TEVA SANTÉ	FR
OFLOXACINE ARROW 200 mg, comprimé pelliculé sécable	not available	NL 28505	ARROW GENERIQUES	FR
OFLOXACINE RANBAXY 200 mg, comprimé pelliculé sécable	not available	NL 31020	RANBAXY PHARMACIE GENERIQUES	FR
OFLOXACINE ALMUS 200 mg, comprimé pelliculé sécable	not available	3400937693622	BIOGARAN	FR
OFLOXACINE ALMUS 200 mg, comprimé pelliculé sécable	not available	3400957000387	BIOGARAN	FR
OFLOXACINE ALMUS 200 mg, comprimé pelliculé sécable	not available	3400957000219	BIOGARAN	FR
OFLOXACINE SANDOZ 200 mg, comprimé pelliculé sécable	not available	34009 364 529 8 5	SANDOZ	FR
OFLOXACINE SANDOZ 200 mg, comprimé pelliculé sécable	not available	34009 565 546 7 6	SANDOZ	FR
OFLOXACINE SANDOZ 200 mg, comprimé	not available	34009 565 547 3 7	SANDOZ	FR

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pelliculé sécable				
OFLOXACINE EG 200 mg, comprimé pelliculé sécable	not available	NL28829	EG LABO LABORATOIRES EUROGENERICS - DO NOT USE	FR
OFLOXACINE AGUETTANT 200 mg/40 ml, solution pour perfusion	not available	34009 566 774 3 6	LABORATOIRE AGUETTANT	FR
OFLOXACINE AGUETTANT 200 mg/40 ml, solution pour perfusion	not available	34009 550 552 4 2	LABORATOIRE AGUETTANT	FR
OFLOXACINE AGUETTANT 200 mg/40 ml, solution pour perfusion	not available	34009 566 776 6 5	LABORATOIRE AGUETTANT	FR
OFLOXACINE BIOGARAN 200 mg, comprimé pelliculé sécable	not available	34009 361 798 8 2	BIOGARAN	FR
OFLOXACINE BIOGARAN 200 mg, comprimé pelliculé sécable	not available	34009 361 799 4 3	BIOGARAN	FR
OFLOXACINE BIOGARAN 200 mg, comprimé pelliculé sécable	not available	3400956480883	BIOGARAN	FR
OFLOXACINE ZENTIVA 200 mg, comprimé pelliculé sécable	not available	34009 566 673 2 1	ZENTIVA FRANCE	FR
OFLOXACINE ZENTIVA 200 mg, comprimé pelliculé sécable	not available	34009 367 162 8 5	ZENTIVA FRANCE	FR
OFLOXACINE ZENTIVA 200 mg, comprimé pelliculé sécable	not available	34009 367 161 1 7	ZENTIVA FRANCE	FR
OFLOXACINE VIATRIS 200 mg/40 ml, solution pour perfusion	not available	NL27256	VIATRIS SANTE	FR
OFLOCET 200 mg,	not available	34009 555 429 8 8	SANOFI WINTHROP	FR

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comprimé pelliculé sécable			INDUSTRIE	
OFLOCET 200 mg, comprimé pelliculé sécable	not available	34009 329 032 3 8	SANOFI WINTHROP INDUSTRIE	FR
OFLOXACINE EVOLUGEN 200 mg, comprimé pelliculé sécable	not available	376 935-6	EVOLUPHARM	FR
OFLOXACINE EVOLUGEN 200 mg, comprimé pelliculé sécable	not available	570 000-9	EVOLUPHARM	FR
OFLOXACINE EVOLUGEN 200 mg, comprimé pelliculé sécable	not available	570 001-5	EVOLUPHARM	FR
OFLOXACINE CRISTERS 200 mg, comprimé pelliculé sécable	not available	34009 376 734 0 2	CRISTERS	FR
OFLOXACINE CRISTERS 200 mg, comprimé pelliculé sécable	not available	34009 569 883 8 9	CRISTERS	FR
OFLOXACINE VIATRIS 200 mg, comprimé pelliculé sécable	not available	NL27098	VIATRIS SANTE	FR
MONOFLOCET 200 mg, comprimé pelliculé	not available	34009 339 124 8 2	SANOFI WINTHROP INDUSTRIE	FR
Tabrin	not available	8562/06-02-2007	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
Tabrin	not available	8562/06-02-2007	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
Tabrin	not available	8562/06-02-2007	SANOFI-AVENTIS MONOPROSOPI A.E.B.E	GR
Tarivid-Richter 200 mg filmdoublette	not available	OGYI-T-3856/01	GEDEON RICHTER PLC.	HU
Zanocin 200 mg plêvele dengtos tabletés	not available	LT/1/96/2828/001	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	LT
OFLOXIN 200 mg plêvele dengtos tabletés	not available	LT/1/2000/2357/001	ZENTIVA, K.S.	LT
OFLOXIN 200 mg plêvele	not available	LT/1/2000/2357/002	ZENTIVA, K.S.	LT

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dengtos tabletės				
Tarivid 200 mg comprimés pelliculés	not available	0113486	SANOFI BELGIUM	LU
Ofloxacin EG 200 mg comprimés pelliculés	AT/H/0748/001	2004050016	EUROGENERICS N.V./S.A.	LU
Ofloxacin EG 400 mg comprimés pelliculés	AT/H/0748/002	2004050017	EUROGENERICS N.V./S.A.	LU
OFLOXIN 200 mg apvalkotās tabletes	not available	98-0852	ZENTIVA, K.S.	LV
ZANOCIN 200 mg apvalkotās tabletes	not available	97-0216	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	LV
Medofloxine 200 mg apvalkotās tabletes	not available	02-0290	MEDOCHEMIE LTD.	LV
Ofloxacin 400 PCH, filmomhulde tabletten 400 mg	NL/H/4742/002	RVG 27572	PHARMACHEMIE B.V	NL
Ofloxacin 200 PCH, filmomhulde tabletten 200 mg	NL/H/4742/001	RVG 27571	PHARMACHEMIE B.V	NL
Ofloxacin Mylan 200 mg, filmomhulde tabletten	NL/H/0979/001	RVG 27753	MYLAN PHARMACEUTICALS LIMITED	NL
Ofloxacin Mylan 400 mg, filmomhulde tabletten	NL/H/0979/002	RVG 27754	MYLAN PHARMACEUTICALS LIMITED	NL
Tarivid 200, 200 mg, tabletki powlekane	not available	R/1112	SANOFI-AVENTIS DEUTSCHLAND GMBH	PL
Tarivid 200, 200 mg, tabletki powlekane	not available	R/1112	SANOFI-AVENTIS DEUTSCHLAND GMBH	PL
Bioquil 200 mg comprimidos revestidos	not available	9752204	LABORATÓRIOS ATRAL, S.A.	PT
Bioquil 200 mg comprimidos revestidos	not available	4653796	LABORATÓRIOS ATRAL, S.A.	PT
Bioquil 200 mg comprimidos revestidos	not available	9752204	LABORATÓRIOS ATRAL, S.A.	PT
Bioquil 200 mg comprimidos revestidos	not available	4653796	LABORATÓRIOS ATRAL, S.A.	PT
Ofloxacin Mylan 200	NL/H/0979/001	4351086	MYLAN, LDA	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
mg Comprimidos revestidos por película				
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167185	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167383	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167284	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167581	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167789	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167888	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167987	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167680	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4167482	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168084	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168183	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168282	MYLAN, LDA	PT

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Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4168381	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4168480	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4168589	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4168688	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4351185	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4168787	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg comprimidos revestidos por película	NL/H/0979/001	4168886	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg comprimidos revestidos por película	NL/H/0979/001	4168985	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg comprimidos revestidos por película	NL/H/0979/001	4169082	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4169181	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4169280	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos revestidos por película	NL/H/0979/001	4169389	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprímidos	NL/H/0979/001	4169488	MYLAN, LDA	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
revestidos por película				
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4169587	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4169686	MYLAN, LDA	PT
Bioquil 400 mg comprimidos revestidos	not available	4818092	LABORATÓRIOS ATRAL, S.A.	PT
Bioquil 400 mg comprimidos revestidos	not available	4818191	LABORATÓRIOS ATRAL, S.A.	PT
Bioquil 400 mg comprimidos revestidos	not available	4817995	LABORATÓRIOS ATRAL, S.A.	PT
Ofloxacină Laropharm 200 mg comprimate filmate	not available	1116/2008/01	LAROPHARM SRL	RO
Zanocin 200 mg comprimate filmate	not available	6230/2014/01	TERAPIA S.A.	RO
Ofloxin 200 mg comprimate filmate	not available	12987/2020/01	ZENTIVA, K.S.	RO
MEDOFLOXINE 200 mg filmom obalené tablety	not available	42/0324/03-S	MEDOCHÉMIE LTD.	SK
Ofloxin 200 filmom obalené tablety	not available	42/0385/96-S	ZENTIVA, K.S.	SK
Ofloxacin 200mg Tablets	not available	PL 17907/0024	BRISTOL LABORATORIES LIMITED	XI
Ofloxacin 400mg Tablets	not available	PL 17907/0025	BRISTOL LABORATORIES LIMITED	XI
Ofloxacin 400 mg Tablets	not available	PL 00289/0354	TEVA UK LIMITED	XI
Ofloxacin 200mg Tablets	not available	PL 00289/0353	TEVA UK LIMITED	XI
Ofloxacin 200 mg Tablets	NL/H/0979/001	PL 04569/0549	GENERIC [UK] LIMITED	XI
Ofloxacin 400 mg Tablets	NL/H/0979/002	PL 04569/0550	GENERIC [UK] LIMITED	XI