



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 December 2021
EMA/502701/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ofloxacin (systemic use)

Procedure no.: PSUSA/00002203/202104



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
Tarivid i. v. 200 mg Infusionslösung	not available	24720.01.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4351086	MYLAN, LDA	PT
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

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 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 filmomhulde tabletten	NL/H/0979/001	BE240125	MYLAN BVBA/SPRL	BE
Ofloxacin Mylan 200 mg filmomhulde tabletten	NL/H/0979/001	BE240134	MYLAN BVBA/SPRL	BE
Ofloxacin Mylan 400 mg filmomhulde tabletten	NL/H/0979/002	BE240152	MYLAN BVBA/SPRL	BE
Ofloxacin Mylan 400 mg filmomhulde tabletten	NL/H/0979/002	BE240143	MYLAN BVBA/SPRL	BE
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

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 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168381	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168480	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168589	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4168688	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4351185	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos 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

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 200 mg Comprimidos revestidos por película	NL/H/0979/001	4169181	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4169280	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4169389	MYLAN, LDA	PT
Ofloxacin Mylan 200 mg Comprimidos revestidos por película	NL/H/0979/001	4169488	MYLAN, LDA	PT
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
Ofloxacin 200 mg Tablets	NL/H/0979/001	PL 04569/0549	GENERICS [UK] LIMITED	XI
Ofloxacin Mylan 200 mg, filmomhulde tabletten	NL/H/0979/001	RVG 27753	MYLAN B.V.	NL
Ofloxacin Mylan 200 mg comprimés pelliculés	NL/H/0979/001	2002100037	MYLAN BVBA/SPRL	LU

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 400 mg, filmomhulde tabletten	NL/H/0979/002	RVG 27754	MYLAN B.V.	NL
Ofloxacin 400 mg Tablets	NL/H/0979/002	PL 04569/0550	GENERICS [UK] LIMITED	XI
Ofloxacin Mylan 400 mg comprimés pelliculés	NL/H/0979/002	2002100038	MYLAN BVBA/SPRL	LU
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 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 pelliculé sécable	not available	34009 565 547 3 7	SANDOZ	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
ОФЛОКСИН 200 mg филмирани таблетки	not available	9900390	ZENTIVA, K.S.	BG
OFLOXACINE EG 200 mg, comprimé pelliculé sécable	not available	NL28829	EG LABO LABORATOIRES EUROGENERICS	FR
OFLOXIN 200 mg apvalkotās tabletes	not available	98-0852	ZENTIVA, K.S.	LV
MEDOFLOXINE 200 mg filmom obalené tablety	not available	42/0324/03-S	MEDOCHEMIE LTD.	SK
Medofloxine 200 mg apvalkotās tabletes	not available	02-0290	MEDOCHEMIE LTD.	LV
Ofloxacin STADA® 400 mg Filmtabletten	not available	54542.02.00	STADAPHARM GMBH	DE
Ofloxacin STADA® 200 mg Filmtabletten	not available	54542.01.00	STADAPHARM GMBH	DE
Ofloxin 200mg film-coated tablets	not available	14408	CODAL SYNTO LTD	CY
Ofloxin 400mg film-coated tablets	not available	19793	CODAL SYNTO LTD	CY

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
Tarivid 200 mg tabletter, filmdrasjerte	not available	7581	SANOFI-AVENTIS NORGE AS	NO
OFLOXACINE MYLAN 200 mg, comprimé pelliculé sécable	not available	NL 27098	MYLAN S.A.S	FR
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
Grenis-Oflo 200 mg filmtableta	not available	OGYI-T-20092/01	PANNONPHARMA KFT.	HU
Ofloxin 200 filmom obalené tablety	not available	42/0385/96-S	ZENTIVA, K.S.	SK
MONOFLOCET 200 mg, comprimé pelliculé	not available	34009 339 124 8 2	SANOFI-AVENTIS FRANCE	FR
Ofloxin 200 mg potahované tablety	not available	42/846/95-C	ZENTIVA, K.S.	CZ

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 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
Ofloxacin STADA 400 mg Filmtabletten	AT/H/0748/002	1-24855	STADA ARZNEIMITTEL GMBH	AT
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

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 200 mg Filmtabletten	AT/H/0748/001	1-24854	STADA ARZNEIMITTEL GMBH	AT
Μεδοφλοξιν 200 mg филмирани таблетки	not available	20060215	MEDOCHEMIE LTD.	BG
Ofloxacin AL 400 Ofloxacin 400 mg pro Filmtablette	not available	46999.02.00	ALIUD PHARMA GMBH	DE
Ofloxacin AL 200 Ofloxacin 200 mg pro Filmtablette	not available	46999.01.00	ALIUD PHARMA GMBH	DE
Ofloxacin-ratiopharm® 100 mg Filmtabletten	not available	46984.00.00	RATIOPHARM GMBH	DE
Cilox 200 mg επικαλυμμένα με υμένιο δισκία	not available	14717	REMEDICA LTD	CY
Tarivid 200mg Film-Coated Tablets	not available	PA 540/76/3	SANOFI-AVENTIS IRELAND LTD. T/A SANOFI	IE
Medofloxine 200 mg film-coated tablets	not available	13357	MEDOCHEMIE LTD.	CY
OFLOXACINE CRISTERS 200 mg, comprimé pelliculé sécable	not available	34009 376 734 0 2	CRISTERS	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
OFLOXACINE CRISTERS 200 mg, comprimé pelliculé sécable	not available	34009 569 883 8 9	CRISTERS	FR
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
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
Tabrin	not available	8562/06-02-2007	SANOFI-AVENTIS AEBE	GR
Tabrin	not available	8562/06-02-2007	SANOFI-AVENTIS AEBE	GR
Tabrin	not available	8562/06-02-2007	SANOFI-AVENTIS AEBE	GR
OFLOXACINE EVOLUGEN 200 mg, comprimé pelliculé sécable	not available	376 935-6	EVOLUPHARM	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
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
Ofloxacină Laropharm 200 mg comprimate filmate	not available	1116/2008/01	LAROPHARM SRL	RO
Ofloxin 200 mg comprimate filmate	not available	12987/2020/01	ZENTIVA, K.S.	RO
OFLOXIN 200 mg plêvele dengtos tabletès	not available	LT/1/2000/2357/001	ZENTIVA, K.S.	LT
OFLOXIN 200 mg plêvele dengtos tabletès	not available	LT/1/2000/2357/002	ZENTIVA, K.S.	LT
OFLOXACINE RANBAXY 200 mg, comprimé pelliculé sécable	not available	NL 31020	RANBAXY PHARMACIE GENERIQUES	FR
OFLOX 100 mg BASICS Filmtabletten	not available	46978.00.00	BASICS GMBH	DE
OFLOX 200 mg BASICS Filmtabletten	DE/H/0312/001	46978.01.00	BASICS 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
OFLOX 400 mg BASICS Filmtabletten	DE/H/0312/002	46978.02.00	BASICS GMBH	DE
ZANOCIN 200 mg apvalkotās tabletes	not available	97-0216	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	LV
Zanocin 200 mg plēvele dengtos tabletēs	not available	LT/1/96/2828/001	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	LT
Zanocin 200 mg comprimatē filmatē	not available	6230/2014/01	TERAPIA S.A.	RO
Ofloxacin 200mg Tablets	not available	PL 17907/0024	BRISTOL LABORATORIES LIMITED	XI
Ofloxacin 400mg Tablets	not available	PL 17907/0025	BRISTOL LABORATORIES LIMITED	XI
OFLOXIN 200, 200 mg dihidroklorīda polimērikatēģa tabletid	not available	403402	ZENTIVA, K.S.	EE
OFLOXACINE CARELIDE 200 mg/40 ml, solution pour perfusion	not available	34009 566 774 3 6	CARELIDE	FR
OFLOXACINE CARELIDE 200 mg/40 ml, solution pour perfusion	not available	34009 550 552 4 2	CARELIDE	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
OFLOXACINE CARELIDE 200 mg/40 ml, solution pour perfusion	not available	34009 566 776 6 5	CARELIDE	FR
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
Tarivid 200 mg Filmdabletten	not available	24720.00.01	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
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
OFLOXACINE BIOGARAN 200 mg, comprimé pelliculé sécable	not available	3400936179882	BIOGARAN	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
OFLOXACINE BIOGARAN 200 mg, comprimé pelliculé sécable	not available	3400936179943	BIOGARAN	FR
OFLOXACINE BIOGARAN 200 mg, comprimé pelliculé sécable	not available	3400956480883	BIOGARAN	FR
Ofloxacin Mylan Pharma 200 mg/40 ml solution pour perfusion	not available	NL 27256	MYLAN S.A.S	FR
Tabrin 200 mg επικαλυμένα με λεπτό υμένιο δισκία.	not available	10896	SANOFI-AVENTIS CYPRUS LTD	CY
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 ALMUS 200 mg, comprimé pelliculé sécable	not available	3400937693622	BIOGARAN	FR
OFLOXACINE ALMUS 200 mg, comprimé pelliculé sécable	not available	3400957000387	BIOGARAN	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
OFLOXACINE ALMUS 200 mg, comprimé pelliculé sécable	not available	3400957000219	BIOGARAN	FR
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
OFLOCET 200 mg, comprimé pelliculé sécable	not available	34009 555 429 8 8	SANOFI-AVENTIS FRANCE	FR
OFLOCET 200 mg, comprimé pelliculé sécable	not available	34009 329 032 3 8	SANOFI-AVENTIS FRANCE	FR
Tarivid-Richter 200 mg filmtabletta	not available	OGYI-T-3856/01	GEDEON RICHTER PLC.	HU
OFLOXACINE ARROW 200 mg, comprimé pelliculé sécable	not available	NL 28505	ARROW GENERIQUES	FR
Tarivid 200 mg comprimés pelliculés	not available	0113486	SANOFI BELGIUM	LU
Medofloxine 200 mg, õhukese polümeerikattega tabletid	not available	485905	MEDOCHÉMIE LTD.	EE

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
Cilox 400 mg επικαλυμμένα με υμένιο δισκία	not available	16037	REMEDICA LTD	CY
Ofloxacin Mylan 200 mg/40 ml, solution pour perfusion	not available	NL 30396	MYLAN S.A.S	FR
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
Bioquil 200 mg comprimidos revestidos	not available	9752204	LABORATÓRIOS ATRAL, S.A.	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 200 mg comprimidos revestidos	not available	4653796	LABORATÓRIOS ATRAL, S.A.	PT
Bioquil 400 mg comprimidos revestidos	not available	4817995	LABORATÓRIOS ATRAL, S.A.	PT