



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 October 2018
EMA/11314/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ciprofloxacin (systemic use)

Procedure no.: PSUSA/00000775/201801



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
Baycip 500 mg comprimidos recubiertos con película	FR/H/0416/002	57.973	BAYER HISPANIA SL	ES
CIFLOX 100 mg/50 mL, solution pour perfusion (IV)	FR/H/0416/010	34009 396 053 9 5	BAYER HEALTHCARE	FR
CIFLOX 100 mg/50 mL, solution pour perfusion (IV)	FR/H/0416/010	34009 396 054 5 6	BAYER HEALTHCARE	FR
CIFLOX 200 mg/100 mL, solution pour perfusion (IV)	FR/H/0416/008	34009 376 227 1 4	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 555 960 5 9	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 364 292 8 4	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 330 272 4 7	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 364 293 4 5	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 364 294 0 6	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 565 381 8 8	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 332 014 2 5	BAYER HEALTHCARE	FR
CIFLOX 250 mg, comprimé pelliculé sécable	FR/H/0416/001	34009 329 812 9 8	BAYER HEALTHCARE	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
CIFLOX 250 mg/5 ml, granulés et solvant pour suspension buvable	FR/H/0416/004	34009 579 160 9 1	BAYER HEALTHCARE	FR
CIFLOX 250 mg/5 ml, granulés et solvant pour suspension buvable	FR/H/0416/004	34009 499 596 5 5	BAYER HEALTHCARE	FR
CIFLOX 400 mg/200 mL, solution pour perfusion (IV)	FR/H/0416/009	34009 376 228 8 2	BAYER HEALTHCARE	FR
CIFLOX 400 mg/200 mL, solution pour perfusion en poche	FR/H/0416/007	34009 579 157 8 0	BAYER HEALTHCARE	FR
CIFLOX 400 mg/200 mL, solution pour perfusion en poche	FR/H/0416/007	34009 579 159 0 2	BAYER HEALTHCARE	FR
CIFLOX 400 mg/200 mL, solution pour perfusion en poche	FR/H/0416/007	34009 579 158 4 1	BAYER HEALTHCARE	FR
CIFLOX 400 mg/200 mL, solution pour perfusion en poche	FR/H/0416/007	34009 572 818 9 2	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 565 382 4 9	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 364 295 7 4	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 364 296 3 5	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 330 271 8 6	BAYER HEALTHCARE	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
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 364 298 6 4	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 329 813 5 9	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 332 013 6 4	BAYER HEALTHCARE	FR
CIFLOX 500 mg, comprimé pelliculé sécable	FR/H/0416/002	34009 555 983 5 0	BAYER HEALTHCARE	FR
CIFLOX 500 mg/5 ml, granulés et solution pour suspension buvable	FR/H/0416/005	34009 344 194 0 9	BAYER HEALTHCARE	FR
CIFLOX 500 mg/5 ml, granulés et solution pour suspension buvable	FR/H/0416/005	34009 579 161 5 2	BAYER HEALTHCARE	FR
CIFLOX 750 mg, comprimé pelliculé	FR/H/0416/003	34009 364 300 0 6	BAYER HEALTHCARE	FR
CIFLOX 750 mg, comprimé pelliculé	FR/H/0416/003	34009 364 299 2 5	BAYER HEALTHCARE	FR
CIFLOX 750 mg, comprimé pelliculé	FR/H/0416/003	34009 348 247 1 5	BAYER HEALTHCARE	FR
CIFLOX 750 mg, comprimé pelliculé	FR/H/0416/003	34009 555 985 8 9	BAYER HEALTHCARE	FR
CIFLOX 750 mg, comprimé pelliculé	FR/H/0416/003	34009 565 383 0 0	BAYER HEALTHCARE	FR
CIFLOX 750 mg, comprimé pelliculé	FR/H/0416/003	34009 330 273 0 8	BAYER HEALTHCARE	FR
Ciprobay 100 mg, 100 mg/50 ml, Infusionslösung	FR/H/0416/010	8242.00.02	BAYER VITAL 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
Ciprobay 200 mg, 200 mg/100 ml, Infusionslösung	FR/H/0416/008	8242.04.02	BAYER VITAL GMBH	DE
Ciprobay 250 mg filmsko obložene tablete	FR/H/0416/001	H/92/00382/001	BAYER D.O.O	SI
Ciprobay 250 mg filmtabletta	FR/H/0416/001	OGYI-T-1441/01	BAYER AG	HU
Ciprobay 250 mg, Filmtabletten	FR/H/0416/001	8242.01.00	BAYER VITAL GMBH	DE
Ciprobay 400 mg, 400 mg/200 ml, Infusionslösung	FR/H/0416/009	8242.05.02	BAYER VITAL GMBH	DE
Ciprobay 400 mg/200 ml raztopina za infundiranje	FR/H/0416/009	H/92/00382/039	BAYER D.O.O	SI
Ciprobay 500 mg filmsko obložene tablete	FR/H/0416/002	H/92/00382/013	BAYER D.O.O	SI
Ciprobay 500 mg filmtabletta	FR/H/0416/002	OGYI-T-1441/02	BAYER AG	HU
Ciprobay 500 mg, Filmtabletten	FR/H/0416/002	8242.02.00	BAYER VITAL GMBH	DE
Ciprobay 500, 500 mg, tabletki powlekane	FR/H/0416/002	R/0900	BAYER AG	PL
Ciprobay 750 mg filmsko obložene tablete	FR/H/0416/003	H/92/00382/025	BAYER D.O.O	SI
Ciprobay 750 mg, Filmtabletten	FR/H/0416/003	8242.03.00	BAYER VITAL GMBH	DE
Ciprobay Saft 10%, 500 mg/5 ml, Granulat und Lösungsmittel zur Herstellung einer Suspension zum Einnehmen	FR/H/0416/005	36212.01.00	BAYER VITAL 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
Ciprobay Saft 5%, 250 mg/5 ml, Granulat und Lösungsmittel zur Herstellung einer Suspension zum Einnehmen	FR/H/0416/004	36212.00.00	BAYER VITAL GMBH	DE
Ciprobay XR 1000 mg, comprimate filmate cu eliberare prelungită	not available	8076/2006/01	BAYER AG	RO
Ciprobay XR 1000 mg, comprimate filmate cu eliberare prelungită	not available	8076/2006/02	BAYER AG	RO
Ciprobay XR 500 mg, comprimate filmate cu eliberare prelungită	not available	8075/2006/01	BAYER AG	RO
Ciprobay XR 500 mg, comprimate filmate cu eliberare prelungită	not available	8075/2006/02	BAYER AG	RO
Ciprofloxacin 250 mg, film coated tablets	not available	PL 21880/0031	MEDREICH PLC	UK
Ciprofloxacin 500 mg film-coated tablets	not available	PL 44041/0007	NOUMED LIFE SCIENCES	UK
Ciprofloxacin 500 mg, film coated tablets	not available	PL 21880/0032	MEDREICH PLC	UK
Ciprofloxacin 750mg, film coated tablets	not available	PL 21880/0033	MEDREICH PLC	UK
Ciprofloxacin Hexal 250 mg - Filmtabletten	not available	1-24121	HEXAL PHARMA GMBH	AT
Ciprofloxacin Hexal 500 mg - Filmtabletten	not available	1-24124	HEXAL PHARMA GMBH	AT
Ciprofloxacin Teva 100 mg filmdrasjerte tabletter	UK/H/0903/001	06-4298	TEVA SWEDEN AB	NO

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
Ciprofloxacin Teva 250 mg filmdrasjerte tabletter	UK/H/0903/002	06-4299	TEVA SWEDEN AB	NO
Ciprofloxacin Teva 500 mg filmdrasjerte tabletter	UK/H/0903/003	06-4300	TEVA SWEDEN AB	NO
Ciprofloxacin Teva 750 mg filmdrasjerte tabletter	UK/H/0903/004	06-4301	TEVA SWEDEN AB	NO
Ciprofloxacin Anages 2 mg/ml solución para perfusión	not available	58123	G.E.S. GENÉRICOS ESPAÑOLES LABORATORIO, S.A.	ES
CIPROFLOXACINO KABI 2 mg/ml solución para perfusión	NL/H/0695/002	68.095	FRESENIUS KABI ESPAÑA S.A.U.	ES
CIPROFLOXACINO KABI 2 mg/ml solución para perfusión	NL/H/0695/003	68.095	FRESENIUS KABI ESPAÑA S.A.U.	ES
Ciproxin 100 mg/ml, granulaat en oplosmiddel voor orale suspensie	FR/H/0416/005	RVG 19342	BAYER BV	NL
Ciproxin 100 mg/ml, granulat och vätska till oral suspension	FR/H/0416/005	12747	BAYER AB	SE
Ciproxin 100 mg/50 mL soluzione per infusione	FR/H/0416/010	026664033	BAYER SPA	IT
Ciproxin 1000 mg compresse a rilascio modificato	not available	026664146	BAYER SPA	IT
Ciproxin 200 mg/100 ml διάλυμα για έγχυση	FR/H/0416/008	11261	BAYER HELLAS SA	CY
Ciproxin 200 mg/100 ml διάλυμα για έγχυση	FR/H/0416/008	36388/25-7-2008	BAYER HELLAS SA	GR
Ciproxin 200 mg/100 mL soluzione per infusione	FR/H/0416/008	026664045	BAYER SPA	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
Ciproxin 250 mg film-coated tablets	FR/H/0416/001	PA 1410/28/2	BAYER LTD	IE
Ciproxin 250 mg film-coated tablets	FR/H/0416/001	MA513/00703	BAYER PLC	MT
Ciproxin 250 mg film-coated tablets	FR/H/0416/001	PL 00010/0146	BAYER PLC	UK
Ciproxin 250 mg Filmtabletten	FR/H/0416/001	1-18295	BAYER AUSTRIA GMBH	AT
Ciproxin 250 mg tabletter, filmdrasjerte	FR/H/0416/001	7564	BAYER AB	NO
Ciproxin 250 mg/5 mL granules and solvent for oral suspension	FR/H/0416/004	PL 00010/0211	BAYER PLC	UK
Ciproxin 250 mg compresse rivestite con film	FR/H/0416/001	026664019	BAYER SPA	IT
Ciproxin 250 mg/5 mL granuli e solvente per sospensione orale	FR/H/0416/004	026664084	BAYER SPA	IT
Ciproxin 400 mg/200 mL soluzione per infusione	FR/H/0416/009	026664058	BAYER SPA	IT
Ciproxin 400 mg/200 ml διάλυμα για έγχυση	FR/H/0416/009	36390/25-7-2008	BAYER HELLAS SA	GR
Ciproxin 5 % orale Suspension	FR/H/0416/004	1-22880	BAYER AUSTRIA GMBH	AT
Ciproxin 50 mg/ml, granulaat en oplosmiddel voor orale suspensie	FR/H/0416/004	RVG 19341	BAYER BV	NL
Ciproxin 50 mg/ml, granulat och vätska till oral suspension	FR/H/0416/004	12746	BAYER AB	SE
Ciproxin 500 mg compresse a rilascio modificato	not available	026664122	BAYER SPA	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
Ciproxin 500 mg film-coated tablets	FR/H/0416/002	PA 1410/28/3	BAYER LTD	IE
Ciproxin 500 mg film-coated tablets	FR/H/0416/002	MA 513/00704	BAYER PLC	MT
Ciproxin 500 mg film-coated tablets	FR/H/0416/002	PL 00010/0147	BAYER PLC	UK
Ciproxin 500 mg filmdragerade tabletter	FR/H/0416/002	10129	BAYER AG	FI
Ciproxin 500 mg Filmtabletten	FR/H/0416/002	1-18296	BAYER AUSTRIA GMBH	AT
Ciproxin 500 mg kalvopäällysteiset tabletit	FR/H/0416/002	10129	BAYER AG	FI
Ciproxin 500 mg tabletter, filmdrasjerte	FR/H/0416/002	7565	BAYER AB	NO
Ciproxin 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	FR/H/0416/002	11264	BAYER HELLAS SA	CY
Ciproxin 500 mg επικαλυμμένα με λεπτό υμένιο δισκία	FR/H/0416/002	36383/25-7-2008	BAYER HELLAS SA	GR
Ciproxin 500 mg/5 mL κοκκία και διαλύτης για πόσιμο εναιώρημα	FR/H/0416/005	36398/25-7-2008	BAYER HELLAS SA	GR
Ciproxin 500 mg compresse rivestite con film	FR/H/0416/002	026664134	BAYER SPA	IT
Ciproxin 500 mg compresse rivestite con film	FR/H/0416/002	026664021	BAYER SPA	IT
Ciproxin 500 mg/5 mL granuli e solvente per sospensione orale	FR/H/0416/005	026664072	BAYER SPA	IT
Ciproxin 750 mg film-coated tablets	FR/H/0416/003	PL 00010/0148	BAYER PLC	UK

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
Ciproxin 750 mg compresse rivestite con film	FR/H/0416/003	026664096	BAYER SPA	IT
Ciproxin 750 mg film-coated tablets	FR/H/0416/003	PA 1410/28/4	BAYER LTD	IE
Ciproxin solution for infusion	FR/H/0416/010	MA 513/00701	BAYER PLC	MT
Ciproxin solution for infusion	FR/H/0416/008	MA 513/00705	BAYER PLC	MT
Ciproxin solution for infusion	FR/H/0416/010	PL 00010/0150	BAYER PLC	UK
Ciproxin solution for infusion	FR/H/0416/008	PL 00010/0150	BAYER PLC	UK
Ciproxin solution for infusion	FR/H/0416/009	PL 00010/0150	BAYER PLC	UK
Ciproxin Solution for Infusion 2mg/ml, 100ml	FR/H/0416/008	PA 1410/28/6	BAYER LTD	IE
Ciproxin Solution for Infusion 2mg/ml, 200ml	FR/H/0416/009	PA 1410/28/7	BAYER LTD	IE
Ciproxina 250 mg comprimidos revestidos por película	FR/H/0416/001	9686717	BAYER PORTUGAL LDA	PT
Ciproxina 250 mg comprimidos revestidos por película	FR/H/0416/001	9686741	BAYER PORTUGAL LDA	PT
Ciproxina 500 mg comprimidos revestidos por película	FR/H/0416/002	9686725	BAYER PORTUGAL LDA	PT
Ciproxina 500 mg comprimidos revestidos por película	FR/H/0416/002	9686758	BAYER PORTUGAL LDA	PT
Ciproxina 750 mg comprimidos revestidos por película	FR/H/0416/003	9686733	BAYER PORTUGAL 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
Ciproxine 200 mg/100 ml oplossing voor infusie	FR/H/0416/008	BE146386	BAYER SA NV	BE
Ciproxine 200 mg/100 ml solution pour perfusion	FR/H/0416/008	BE146386	BAYER SA NV	BE
Ciproxine 200 mg/100 ml solution pour perfusion	FR/H/0416/008	1995063214	BAYER SA NV	LU
Ciproxine 200 mg/100 ml Infusionslösung	FR/H/0416/008	BE146386	BAYER SA NV	BE
Ciproxine 200 mg/100 ml Infusionslösung	FR/H/0416/008	1995063214	BAYER SA NV	LU
Ciproxine 250 mg comprimés pelliculés	FR/H/0416/001	BE146657	BAYER SA NV	BE
Ciproxine 250 mg comprimés pelliculés	FR/H/0416/001	0442/99/04/5247	BAYER SA NV	LU
Ciproxine 250 mg filmomhulde tabletten	FR/H/0416/001	BE146657	BAYER SA NV	BE
Ciproxine 250 mg Filmtabletten	FR/H/0416/001	BE146657	BAYER SA NV	BE
Ciproxine 250 mg Filmtabletten	FR/H/0416/001	0442/99/04/5247	BAYER SA NV	LU
Ciproxine 50 mg/ml granulaat en oplosmiddel voor suspensie voor oraal gebruik	FR/H/0416/004	BE213507	BAYER SA NV	BE
Ciproxine 50 mg/ml granulés et solvant pour suspension buvable	FR/H/0416/004	BE213507	BAYER SA NV	BE
Ciproxine 50 mg/ml granulés et solvant pour suspension buvable	FR/H/0416/004	2002060013	BAYER SA NV	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
Ciproxine 50 mg/ml Granulat und Lösungsmittel zur Herstellung einer Suspension zum Einnehmen	FR/H/0416/004	BE213507	BAYER SA NV	BE
Ciproxine 50 mg/ml Granulat und Lösungsmittel zur Herstellung einer Suspension zum Einnehmen	FR/H/0416/004	2002060013	BAYER SA NV	LU
Ciproxine 500 mg comprimés pelliculés	FR/H/0416/002	BE148461	BAYER SA NV	BE
Ciproxine 500 mg comprimés pelliculés	FR/H/0416/002	1999045248	BAYER SA NV	LU
Ciproxine 500 mg filmomhulde tabletten	FR/H/0416/002	BE148461	BAYER SA NV	BE
Ciproxine 500 mg Filmtabletten	FR/H/0416/002	BE148461	BAYER SA NV	BE
Ciproxine 500 mg Filmtabletten	FR/H/0416/002	1999045248	BAYER SA NV	LU
Ciproxine IV Flexibag 400 mg/200 ml oplossing voor infusie	FR/H/0416/007	BE339884	BAYER SA NV	BE
Ciproxine IV Flexibag 400 mg/200 ml solution pour perfusion	FR/H/0416/007	BE339884	BAYER SA NV	BE
Ciproxine IV Flexibag 400 mg/200 ml solution pour perfusion	FR/H/0416/007	0442/00/10/0026	BAYER SA NV	LU
Ciproxine IV Flexibag 400 mg/200 ml Infusionslösung	FR/H/0416/007	BE339884	BAYER SA NV	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
Ciproxine IV Flexibag 400 mg/200 ml Infusionslösung	FR/H/0416/007	0442/00/10/0026	BAYER SA NV	LU
CIPROXINÒ XR 1000 mg δισκία ελεγχόμενης αποδέσμευσης	not available	36401/25-07-2008	BAYER HELLAS SA	GR
CITERAL 100 mg/10 ml koncentrat za otopinu za infuziju	not available	HR-H-985664083	ALKALOID D.O.O.	HR
Estecina 200 mg/100 ml solução para perfusão	not available	2315489	LABORATÓRIOS NORMON, S.A.	PT
Estecina 200 mg/100 ml solução para perfusão	not available	5208434	LABORATÓRIOS NORMON, S.A.	PT
Estecina 200 mg/100 ml solução para perfusão	not available	2315489	LABORATÓRIOS NORMON, S.A.	PT
Estecina 200 mg/100 ml solução para perfusão	not available	5208434	LABORATÓRIOS NORMON, S.A.	PT
Estecina 400 mg/200 ml solução para perfusão	not available	3125689	LABORATÓRIOS NORMON, S.A.	PT
Estecina 400 mg/200 ml solução para perfusão	not available	5208442	LABORATÓRIOS NORMON, S.A.	PT
Estecina 400 mg/200 ml solução para perfusão	not available	3125689	LABORATÓRIOS NORMON, S.A.	PT
Estecina 400 mg/200 ml solução para perfusão	not available	5208442	LABORATÓRIOS NORMON, S.A.	PT
GLOBUCE 250 mg comprimidos recubiertos con película	not available	58880	ALFASIGMA ESPAÑA, S.L.	ES
GLOBUCE 500 mg comprimidos recubiertos con película	not available	58879	ALFASIGMA ESPAÑA, S.L.	ES
GLOBUCE 750 mg comprimidos recubiertos con película	not available	58881	ALFASIGMA ESPAÑA, S.L.	ES

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
Ibixacin 250 mg compresse rivestite con film	not available	038360018	IBI G. LORENZINI SPA	IT
Ibixacin 500 mg compresse rivestite con film	not available	038360020	IBI G. LORENZINI SPA	IT
Ibixacin 750 mg compresse rivestite con film	not available	038360032	IBI G. LORENZINI SPA	IT
UNIFLOX, comprimé pelliculé sécable	not available	336 523.9	BAYER HEALTHCARE	FR
Ципробай 250 mg филмирани таблетки	FR/H/0416/001	20010820	BAYER AG	BG
Ципробай 500 mg филмирани таблетки	FR/H/0416/002	20010821	BAYER AG	BG
Ципрофлоксацин Ауробиндо 750 mg Филмирана таблетки	PT/H/1324/003	20160096	AUROBINDO PHARMA (MALTA) LIMITED	BG