



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 October 2018
EMA/684413/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ciprofloxacin (topical use)

Procedure no.: PSUSA/00000776/201801



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
Cetraflux 3 mg/ml colirio en solución en envase unidos	ES/H/0174/001	76474	LABORATORIOS SALVAT, S.A.	ES
Cetraflux 3 mg/ml colírio, solução em recipiente unidose	ES/H/0174/001	5594247	LABORATORIOS SALVAT, S.A.	PT
Cetraflux 3 mg/ml colírio, solução em recipiente unidose	ES/H/0174/001	5594254	LABORATORIOS SALVAT, S.A.	PT
Cetraflux 3 mg/ml colírio, solução em recipiente unidose	ES/H/0174/001	5594262	LABORATORIOS SALVAT, S.A.	PT
Cetraflux 3 mg/ml collirio, soluzione in contenitore monodose	ES/H/0174/001	042055018	LABORATORIOS SALVAT, S.A.	IT
Cetraflux 3 mg/ml collirio, soluzione in contenitore monodose	ES/H/0174/001	042055020	LABORATORIOS SALVAT, S.A.	IT
Cetraflux 3 mg/ml collirio, soluzione in contenitore monodose	ES/H/0174/001	042055032	LABORATORIOS SALVAT, S.A.	IT
Cetraxal 2 mg/ml ear drops solution in single-dose container	NL/H/1420/001	PL35533/0130	ASPIRE PHARMA LIMITED	UK
Cetraxal 2 mg/ml eyrnadropar, lausn í stakskammtailáti	NL/H/1420/001	IS/1/13/010/01	LABORATORIOS SALVAT, S.A.	IS
Cetraxal 2 mg/ml korvatipat, liuos, kerta-annospakkauksessa	NL/H/1420/001	30865	LABORATORIOS SALVAT, S.A.	FI
Cetraxal 2 mg/ml oordruppels, oplossing	NL/H/1420/001	RVG 102959	LABORATORIOS SALVAT, S.A.	NL
Cetraxal 2 mg/ml øredråper oppløsning i endosebeholder	NL/H/1420/001/E/002	12-9143	LABORATORIOS SALVAT, S.A.	NO

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Cetraxal 2 mg/ml öronddroppar, lösning i endosbehållare	NL/H/1420/001	48199	LABORATORIOS SALVAT, S.A.	SE
CETRAXAL 2 mg/ml, solution pour instillation auriculaire	NL/H/1420/001	415 134-5	BIOCODEX	FR
CETRAXAL 2MG/ML ωτικές σταγόνες, διάλυμα	NL/H/1420/001/DC	45796/2-6-2016	VIANEX S.A.	GR
CETRAXAL 2MG/ML ωτικές σταγόνες, διάλυμα	NL/H/1420/001/DC	45796/2-6-2016	VIANEX S.A.	GR
Cetraxal, 2 mg/ml, krople do uszu, roztwór	NL/H/1420/001	20161	TACTICA PHARMACEUTICAL SP. Z O.O.	PL
Cetraxal, øredråber, opløsning i enkeltdosisbeholder	NL/H/1420/001	51068	LABORATORIOS SALVAT, S.A.	DK
CIFLOXACIN 3mg/mL Ωτικές σταγόνες, διάλυμα	not available	97413	VERISFIELD (UK) LTD	GR
Cilox 3 mg/g øyesalve	not available	00-4370	NOVARTIS NORGE AS	NO
Cilox 3 mg/ml øredråper, opløsning	not available	01-840	NOVARTIS NORGE AS	NO
Cilox 3 mg/ml øyedråper, oppløsning	not available	8129	NOVARTIS NORGE AS	NO
CILOXAN 0,3 POUR CENT, collyre	not available	34009 337 375 3 5	NOVARTIS PHARMA S.A.S.	FR
CILOXAN 0,3%, pommade ophtalmique	not available	359 227-7	NOVARTIS PHARMA S.A.S.	FR
CILOXAN 0.3% w/v eye drops, solution	not available	PL 00101/0994	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
Ciloxan 3 mg/g ögonsalva	not available	16500	NOVARTIS SVERIGE AB	SE
CILOXAN 3 mg/g, oogzalf	not available	BE239127	NOVARTIS PHARMA N.V.	BE
CILOXAN 3 mg/g, pommade ophtalmique	not available	BE239127	NOVARTIS PHARMA N.V.	BE

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CILOXAN 3 mg/g, pommade ophtalmique	not available	2010050779	NOVARTIS PHARMA N.V.	LU
Ciloxan 3 mg/ml acu pilieni, šķidums	not available	00-0815	SA ALCON-COUVREUR NV	LV
Ciloxan 3 mg/ml akių lašai (tirpalas)	not available	LT/1/98/3165/001	SIA "NOVARTIS BALTICS"	LT
CILOXAN 3 mg/ml Augen- und Ohrentropfen, Lösung	not available	BE163502	NOVARTIS PHARMA N.V.	BE
CILOXAN 3 mg/ml Augen- und Ohrentropfen, Lösung	not available	2006028399	NOVARTIS PHARMA N.V.	LU
CILOXAN 3 mg/ml ear drops, solution	not available	PA 0013/128/001	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
CILOXAN 3 mg/ml kapi za oko i uho, otopina	not available	HR-H-578076301	NOVARTIS HRVATSKA D.O.O.	HR
CILOXAN 3 mg/ml kapljice za oko, raztopina	not available	H/94/00377/001	SA ALCON-COUVREUR NV	SI
Ciloxan 3 mg/ml ögondroppar, lösning	not available	11625	NOVARTIS SVERIGE AB	SE
Ciloxan 3 mg/ml oldatos szem- és fülcsepp	not available	OGYI-T-7752/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
CILOXAN 3 mg/ml oog-en oordruppels, oplossing	not available	BE163502	NOVARTIS PHARMA N.V.	BE
Ciloxan 3 mg/ml örondroppar, lösning	not available	17194	NOVARTIS SVERIGE AB	SE
Ciloxan 3 mg/ml silmatilgad, lahus	not available	278499	SIA "NOVARTIS BALTICS"	EE
CILOXAN 3 mg/ml solution pour gouttes ophtalmiques et auriculaires	not available	BE163502	NOVARTIS PHARMA N.V.	BE

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CILOXAN 3 mg/ml solution pour gouttes ophtalmiques et auriculaires	not available	2006028399	NOVARTIS PHARMA N.V.	LU
CILOXAN 3 mg/ml, solution pour instillation auriculaire	not available	360 130-3	NOVARTIS PHARMA S.A.S.	FR
CILOXAN 3mg/g Eye Ointment	not available	PL 00101/0995	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
CILOXAN Oční/ušní kapky, roztok	not available	64/428/93-C	NOVARTIS, S.R.O.	CZ
CILOXAN OTIC, ear drops 3 mg/ml, solution	not available	MA 088/05402	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Ciloxan, 3 mg/g, maść do oczu	not available	14263	NOVARTIS POLAND SP. Z O. O.	PL
Ciloxan, 3 mg/ml, krople do oczu, roztwór	not available	9113	NOVARTIS POLAND SP. Z O. O.	PL
CILOXAN, eye drops 3 mg/ml	not available	MA 088/05401	NOVARTIS PHARMACEUTICALS UK LIMITED	MT
Ciloxan, øjendråber, opløsning	not available	15071	NOVARTIS HEALTHCARE A/S	DK
Ciloxan, øjensalve	not available	31697	NOVARTIS HEALTHCARE A/S	DK
Ciloxan, øredråber, opløsning	not available	32222	NOVARTIS HEALTHCARE A/S	DK
CILOXAN® 0.3% w/v eye drops, solution	not available	19630	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
CILOXAN® 3 mg/ml Augentropfen	not available	27227.00.00	NOVARTIS PHARMA GMBH	DE
CILOXAN® 3 mg/ml Ohrentropfen, Lösung	not available	51202.00.00	NOVARTIS PHARMA GMBH	DE

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CIPROXINA Simple 3 mg/ml gotas óticas en solución	not available	64.940	NOVARTIS FARMACÉUTICA S.A.	ES
DROLL 1 mg Ωπικές σταγόνες, διάλυμα	AT/H/0685/001	80735/15/30-01-2017	GALENICA SA	GR
INFECTOCIPRO® 2 mg/ml Ohrentropfen Lösung im Einzeldosisbehältnis	NL/H/1420/001	74133.00.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
OFTACILOX 0,3% collirio, soluzione	not available	028476012	NOVARTIS FARMA S.P.A.	IT
OFTACILOX 0,3% unguento oftalmico	not available	028476024	NOVARTIS FARMA S.P.A.	IT
OFTACILOX 3 mg/g pomada oftálmica	not available	64.904	NOVARTIS FARMACÉUTICA S.A.	ES
OFTACILOX 3 mg/g Pomada Oftálmica	not available	3641982	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
OFTACILOX 3 mg/ml colirio en solución	not available	60.608	NOVARTIS FARMACÉUTICA S.A.	ES
OFTACILOX 3 mg/ml Colírio, solução	not available	3549185	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
OFTACILOX 3 mg/ml gocce auricolari, soluzione	not available	028476036	NOVARTIS FARMA S.P.A.	IT
Unicexal 2 mg/ml gocce auricolari, soluzione	NL/H/1420/001	040648014	ITALCHIMICI S.P.A.	IT
ЦИЛОКСАН 3 mg/ml капли за очи и уши, разтвор	not available	II-2955	NOVARTIS PHARMA GMBH	BG