



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 November 2024
EMA/563900/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance: ciprofloxacin / fluocinolone acetonide

Procedure no.: PSUSA/00000772/202404



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
InfectoCiproCort 3 mg/ml + 0,25 mg/ml Ohrentropfen, Lösung	ES/H/0166/001	138434	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	AT
Infalin duo 3 mg/ml + 0,25 mg/ml ušní kapky, roztok	ES/H/0166/001	69/673/12-C	LABORATORIOS SALVAT, S.A.	CZ
Infalin Duo 3 mg/ml + 0,25 mg/ml ušní kapky, roztok v jednodávkovém obalu	ES/H/0166/002	69/035/17-C	LABORATORIOS SALVAT, S.A.	CZ
InfectoCiproCort 3 mg/ml + 0,25 mg/ml Ohrentropfen, Lösung im Einzeldosisbehälter	ES/H/0166/002	99969.00.00	PÄDIA GMBH	DE
InfectoCiproCort 3 mg/ml + 0,25 mg/ml Ohrentropfen, Lösung	ES/H/0166/001	90218.00.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Cetraxal Comp, øredråber, opløsning	ES/H/0166/001	50729	POA PHARMA SCANDINAVIA AB	DK
Cetraxal Comp ukonserveret	ES/H/0166/002	59139	POA PHARMA SCANDINAVIA AB	DK
Bonadix 3 mg/0,25 mg/ml kõrvatilgad, lahus üheannuselises konteineris	ES/H/0166/002	1097323	ORIVAS	EE
Synalotic 3 mg/ml + 0,25 mg/ml gotas óticas en solución	not available	64.655	INDUSTRIAL FARMACEUTICA CANTABRIA, S.A.	ES
Aceoto Plus 3 / 0,25 mg/ml gotas óticas en solución	not available	64658	ZAMBON, S.A.U.	ES
Cetraxal Plus 3 mg/ml + 0,25 mg/ml gotas óticas en solución	ES/H/0166/001	64.657	LABORATORIOS SALVAT, S.A.	ES
Cetraxal Plus 3 mg/ml +	ES/H/0166/002	83244	LABORATORIOS SALVAT,	ES

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0,25 mg/ml gotas óticas en solución en envase unidos			S.A.	
Cetraxal Comp 3 mg/ml + 0,25 mg/ml korvatipat, liuos kerta-annospakkaus	ES/H/0166/002	34960	POA PHARMA SCANDINAVIA AB	FI
Cetraxal Comp 3 mg/ml + 0,25 mg/ml öronddroppar, lösning i endosbehållare	ES/H/0166/002	34960	POA PHARMA SCANDINAVIA AB	FI
Cetraxal Comp 3 mg/ml + 0,25 mg/ml korvatipat, liuos	ES/H/0166/001	30701	POA PHARMA SCANDINAVIA AB	FI
Cetraxal Comp 3 mg/ml + 0,25 mg/ml öronddroppar, lösning	ES/H/0166/001	30701	POA PHARMA SCANDINAVIA AB	FI
CETRAXAL 3 mg/0,25 mg par ml, solution pour instillation auriculaire	ES/H/0166/001	34009 221 806 8 7	LABORATORIOS SALVAT, S.A.	FR
CETRAXAL 3 mg/0,25 mg par mL, solution pour instillation auriculaire en récipient unidose	ES/H/0166/002	34009 301 519 9 0	LABORATORIOS SALVAT, S.A.	FR
Otospon (3 + 0,25) mg/ml ωτικές σταγόνες, διάλυμα	not available	27057/14/17-9-15	VIANEX S.A.	GR
Duoxal 3 mg/ml + 0,25 mg/ml oldatos fülcsepp	not available	OGYI-T-23414/01	GOODWILL PHARMA NYRT.	HU
Cetraxal Comp 3 mg/ml + 0,25 mg/ml eyrnadropar, lausn	ES/H/0166/001	IS/1/12/100/01	POA PHARMA SCANDINAVIA AB	IS
Cetraxal Comp 3 mg/ml + 0,25 mg/ml eyrnadropar, lausn í stakskammtailáti	ES/H/0166/002	IS/1/18/025/01	POA PHARMA SCANDINAVIA AB	IS
Cexidal 3 mg/ml + 0,25 mg/ml gocce auricolari	not available	037231065	INFECTOPHARM ARZNEIMITTEL UND	IT

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soluzione in contenitore monodose			CONSILIUM GMBH	
Cexidal 3 mg/ml + 0,25 mg/ml gocce auricolari, soluzione	not available	037231053	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	IT
Bonadix 3 mg/0,25 mg/ml ausų lašai (tirpalas vienadozėje talpyklėje)	ES/H/0166/002	LT/1/22/5076/001	ORIVAS	LT
Bonadix 3 mg/0,25 mg/ml ausu pilieni, šķidums vienas devas iepakojumā	ES/H/0166/002	22-0198	ORIVAS	LV
Cetraxal Comp 3 mg/ml + 0,25 mg/ml øredråper, oppløsning	ES/H/0166/001	12-9039	POA PHARMA SCANDINAVIA AB	NO
Cetraxal Comp 3 mg/ml + 0,25 mg/ml øredråper, oppløsning i endosebeholder	ES/H/0166/002	17-11563	POA PHARMA SCANDINAVIA AB	NO
Cetraxal Plus, 3 mg/ml + 0,25 mg/ml, krople do uszu, roztwór	ES/H/0166/001	20095	TACTICA PHARMACEUTICALS SP. Z O.O.	PL
Cetraxal Plus, 3 mg/ml + 0,25 mg/ml, krople do uszu, roztwór w pojemniku jednodawkowym	ES/H/0166/002	24917	TACTICA PHARMACEUTICALS SP. Z O.O.	PL
Ciprotic, 3 mg/ml + 0,25 mg/ml, krople do uszu, roztwór	not available	26333	SOLINEA SP. Z O.O. SP. K.	PL
Cetraxal Duo 3 mg/ml + 0,25 mg/ml gotas auriculares, solução	ES/H/0166/001	5755533	LABORATORIOS SALVAT, S.A.	PT
Cetraxal Duo 3 mg/ml + 0,25 mg/ml gotas auriculares solução em recipiente unidose	ES/H/0166/002	5755541	LABORATORIOS SALVAT, S.A.	PT
Cexidal 3 mg/ml/0,25	ES/H/0166/001	10781/2018/01	LABORATORIOS SALVAT,	RO

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mg/ml, picături auriculare soluție			S.A.	
Cexidal 3 mg/ml + 0,25 mg/ml picături auriculare, soluție în recipient unidoză	ES/H/0166/002	10781/2018/01	LABORATORIOS SALVAT, S.A.	RO
Cetraxal Comp 3 mg/ml + 0,25 mg/ml öronddroppar, lösning i endosbehållare	ES/H/0166/002	56004	POA PHARMA SCANDINAVIA AB	SE
Cetraxal Comp 3 mg/ml + 0,25 mg/ml öronddroppar, lösning	ES/H/0166/001	47982	POA PHARMA SCANDINAVIA AB	SE
Infalin duo 3 mg/ml + 0,25 mg/ml ušná roztoková instilácia	ES/H/0166/001	69/0387/12-S	LABORATORIOS SALVAT, S.A.	SK
Infalin duo 3 mg/ml + 0,25 mg/ml ušná roztoková instilácia v jednodávkovom obale	ES/H/0166/002	15/0101/18-S	LABORATORIOS SALVAT, S.A.	SK
Cetraxal Plus 3 mg/ml + 0.25 mg/ml ear drops solution in single-dose container	ES/H/0166/002	PL35533/0133	ASPIRE PHARMA LIMITED	XI