



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 December 2021
EMA/724898/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexamethasone / netilmicin

Procedure no.: PSUSA/00010854/202104



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
NETILDEX 3 mg /ml / 1 mg/ ml collirio, soluzione	not available	036452023	SIFI S.P.A.	IT
NETILDEX 3 mg /ml / 1 mg/ ml collirio, soluzione	not available	036452035	SIFI S.P.A.	IT
NETILDEX 3 mg /ml / 1 mg/ ml collirio, soluzione	not available	036452062	SIFI S.P.A.	IT
Galminor 3 mg/ml + 1 mg/ml collirio, soluzione	not available	044877013	GENETIC SPA	IT
Galminor 3 mg/ml + 1 mg/ml collirio, soluzione	not available	044877025	GENETIC SPA	IT
Slaner 3mg/ml + 1 mg/ml collirio, soluzione	not available	044879017	GENETIC SPA	IT
Slaner 3mg/ml + 1 mg/ml collirio, soluzione	not available	044879029	GENETIC SPA	IT
IPOKIMA 3mg/ml + 1 mg/ml collirio, soluzione	not available	044881011	DOC GENERICI S.R.L.	IT
IPOKIMA 3mg/ml + 1 mg/ml collirio, soluzione	not available	044881023	DOC GENERICI S.R.L.	IT
Netildex 3 mg/ml / 1 mg/ml gel oftalmico	not available	036452047	SIFI S.P.A.	IT
Netildex 3 mg/ml / 1 mg/ml gel oftalmico	not available	036452050	SIFI S.P.A.	IT
Netildex 3 mg/ml / 1 mg/ml gel oftalmico	not available	036452074	SIFI S.P.A.	IT
Netildex 3 mg/1 mg/ml picături oftalmice, soluție	not available	11663/2019/01	SIFI S.P.A.	RO
Netildex 3 mg/1 mg/ml picături oftalmice, soluție în flacon unidoză	not available	11662/2019/01	SIFI S.P.A.	RO
Netildex 3 mg/1 mg/ml picături oftalmice, soluție în flacon unidoză	not available	11662/2019/02	SIFI S.P.A.	RO
DEXAMÉTHASONE/NETILMICINE NEWLINE PHARMA 1 mg/3 mg par ml, collyre en solution	PT/H/2242/001	NL49769	NEWLINE PHARMA S.L.	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
Dexametasona + Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml colírio, solução.	PT/H/2242/001	5794748	NEWLINE PHARMA S.L.	PT
NETDEX 3 mg/ml + 1 mg/ml colirio en solución	PT/H/2242/001	84980	SIFI S.P.A.	ES
Netilmicin/Dexamethasone NewLine Pharma 3 mg/ml + 1 mg/ml Οφθαλμικές σταγόνες, διάλυμα.	PT/H/2242/001	53333/15-06-2020	NEWLINE PHARMA S.L.	GR
Netilmicin/Dexamethasone NewLine Pharma 3 mg/ml + 1 mg/ml Οφθαλμικές σταγόνες, διάλυμα	PT/H/2242/001	023326	NEWLINE PHARMA S.L.	CY
NETILDEX 3 mg /ml / 1 mg/ ml collirio, soluzione	not available	036452011	SIFI S.P.A.	IT
DEXAMÉTHASONE/NETILMICINE NEWLINE PHARMA 1 mg/3 mg par ml, collyre en solution en récipient unidose	PT/H/2242/002	NL49770	NEWLINE PHARMA S.L.	FR
Dexametasona + Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml colírio, solução em recipiente unidose.	PT/H/2242/002	5794755	NEWLINE PHARMA S.L.	PT
Dexametasona + Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml colírio, solução em recipiente unidose.	PT/H/2242/002	5794763	NEWLINE PHARMA S.L.	PT
Netilmicin/Dexamethasone NewLine Pharma 3 mg/ml + 1 mg/ml Οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης.	PT/H/2242/002	53334/15-06-2020	NEWLINE PHARMA S.L.	GR
Netilmicina/Dexametasona NewLine Pharma 3 mg/ml + 1 mg/ml gel oftálmico en envase unidos	PT/H/2360/001	85629	NEWLINE PHARMA 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
Netilmicin/Dexamethasone NewLine Pharma 3 mg/ml + 1 mg/ml Οφθαλμικές σταγόνες, διάλυμα σε περιέκτη μίας δόσης.	PT/H/2242/002	023327	NEWLINE PHARMA S.L.	CY
DEXAMETHASONE/NETILMICINE NEWLINE PHARMA 1 mg/3 mg par ml, gel ophtalmique	PT/H/2360/001	NL51488	NEWLINE PHARMA S.L.	FR
Netilmicin/Dexamethason NewLine Pharma 3 mg/ml + 1 mg/ml Augengel	PT/H/2360/001	2204380.00.00	NEWLINE PHARMA S.L.	DE
Netilmicina/Dexametasona NewLine Pharma 3 mg/ml + 1 mg/ml gel oftálmico en envase unidos	PT/H/2360/001	85629	NEWLINE PHARMA S.L.	ES
Dexametazona/Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml gel oftálmico în recipient unidoza	DCP PT/H/2360/001/DC	13523/2020/01	NEWLINE PHARMA S.L.	RO
Dexametazona/Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml gel oftálmico în recipient unidoza	DCP PT/H/2360/001/DC	13523/2020/02	NEWLINE PHARMA S.L.	RO
Dexametazona/Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml gel oftálmico în recipient unidoza	DCP PT/H/2360/001/DC	13523/2020/03	NEWLINE PHARMA S.L.	RO
Dexametasona + Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml gel oftálmico em recipiente unidose	PT/H/2360/001	5808431	NEWLINE PHARMA S.L.	PT
Dexametasona + Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml gel oftálmico em recipiente unidose	PT/H/2360/001	5808449	NEWLINE PHARMA S.L.	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
Dexametasona + Netilmicina NewLine Pharma 1 mg/ml + 3 mg/ml gel oftálmico em recipiente unidose	PT/H/2360/001	5808456	NEWLINE PHARMA S.L.	PT
Netilmicin/Dexamethasone NewLine Pharma 3 mg/ml / 1 mg/ml οφθαλμική γέλη	PT/H/2360/001	137000/20/04-01-2021	NEWLINE PHARMA S.L.	GR
Netilmicin/Dexamethasone NewLine Pharma 3 mg/ml / 1 mg/ml οφθαλμική γέλη	PT/H/2360/001	023356	NEWLINE PHARMA S.L.	CY
Netildex 3 mg/1 mg/ml picături oftalmice, soluție	not available	11663/2019/01	SIFI S.P.A.	RO
Netildex 3 mg/1 mg/ml picături oftalmice, soluție în flacon unidoză	not available	11662/2019/01	SIFI S.P.A.	RO
Netildex 3 mg/1 mg/ml picături oftalmice, soluție în flacon unidoză	not available	11662/2019/02	SIFI S.P.A.	RO