



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 December 2021
EMA/609316/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tobramycin (ophthalmic and otic use)

Procedure no.: PSUSA/00009317/202103

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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
TOBEX -Augensalbe	not available	1-21066	NOVARTIS PHARMA GMBH	AT
TOBEX - Augentropfen	not available	1-19633	NOVARTIS PHARMA GMBH	AT
TOBRAVISC 3 mg/ml oogdruppels, oplossing	not available	BE264336	NOVARTIS PHARMA N.V.	BE
TOBRAVISC 3 mg/ml collyre en solution	not available	BE264336	NOVARTIS PHARMA N.V.	BE
TOBRAVISC 3 mg/ml Augentropfen	not available	BE264336	NOVARTIS PHARMA N.V.	BE
TOBEX 3 mg/g oogzalf	not available	BE125115	NOVARTIS PHARMA N.V.	BE
TOBEX 3 mg/ml oogdruppels, oplossing	not available	BE125176	NOVARTIS PHARMA N.V.	BE
TOBEX 3 mg/g pommade ophtalmique	not available	BE125115	NOVARTIS PHARMA N.V.	BE
TOBEX 3 mg/ml collyre en solution	not available	BE125176	NOVARTIS PHARMA N.V.	BE

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TOBEX 3 mg/g Augensalbe	not available	BE125115	NOVARTIS PHARMA N.V.	BE
TOBEX 3 mg/ml Augentropfen, Lösung	not available	BE125176	NOVARTIS PHARMA N.V.	BE
ТОБРЕКС 3 mg/ml капки за очи, разтвор	not available	9600004	NOVARTIS PHARMA GMBH	BG
ТОБРЕКС 3 mg/g маз за очи	not available	9600005	NOVARTIS PHARMA GMBH	BG
Tobrex® 0,3% w/v, οφθαλμικές σταγόνες, διάλυμα	not available	17322	NOVARTIS IRELAND LIMITED	CY
TOBEX 0,3% w/w, οφθαλμική αλοιφή	not available	17321	NOVARTIS IRELAND LIMITED	CY
TOBEX LA 3 mg/ml oční kapky, roztok	not available	64/257/05-C	NOVARTIS S.R.O.,	CZ
TOBEX 3 mg/ml oční kapky, roztok	not available	64/106/87-C	NOVARTIS S.R.O.,	CZ
TOBEX 3 mg/ml oční mast	not available	64/128/91-C	NOVARTIS S.R.O.,	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
Tobramaxin® Augensalbe 3 mg/g Augensalbe	not available	37896.00.00	NOVARTIS PHARMA GMBH	DE
Tobramaxin® Augensalbe 3 mg/g Augensalbe	not available	37896.00.00	NOVARTIS PHARMA GMBH	DE
Tobrex Depot, depotøjendråber, opløsning	not available	33984	NOVARTIS HEALTHCARE A/S	DK
Tobrex 2x 3 mg/ml silmatilgad, lahus	not available	459305	SIA NOVARTIS BALTICS	EE
Tobrex 3 mg/g silmasalv	not available	353301	SIA "NOVARTIS BALTICS"	EE
TOBEX 3 mg/ml colirio en solución	not available	57.594	NOVARTIS FARMACÉUTICA S.A.	ES
Ursitan 3 mg/ml colirio en solución en envase unidosis	ES/H/0190/001	77752	LABORATORIOS SALVAT, S.A.	ES
TOBEX® UNGÜENTO OFTÁLMICO 3 mg/g pomada oftálmica	not available	57.593	NOVARTIS FARMACÉUTICA S.A.	ES
TOBEXAN 3 mg/ml colirio en solución.	not available	66.421	NOVARTIS FARMACÉUTICA S.A.	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
Tobrex Depot 3 mg/ml silmätipat, liuos	not available	17507	NOVARTIS FINLAND OY	FI
Tobrex Depot 3 mg/ml ögondroppar, lösning	not available	17507	NOVARTIS FINLAND OY	FI
TOBREX 0,3 %, collyre en solution	not available	34009 328 054 3 3	NOVARTIS PHARMA S.A.S.	FR
TOBREX 0,3 %, pommade ophtalmique	not available	3400932805372	NOVARTIS PHARMA S.A.S.	FR
TOBREX 0,3% w/w, οφθαλμική αλοιφή	not available	185270201	NOVARTIS (HELLAS) S.A.C.I.	GR
TOBREX 2x 0,3% w/v, οφθαλμικές σταγόνες, διάλυμα	not available	185270301	NOVARTIS (HELLAS) S.A.C.I.	GR
TOBREX 0,3% w/v, οφθαλμικές σταγόνες, διάλυμα	not available	185270101	NOVARTIS (HELLAS) S.A.C.I.	GR
Tobrex 3 mg/g mast za oko	not available	HR-H-257802614-01	NOVARTIS HRVATSKA D.O.O.	HR
Tobrex 3 mg/ml kapi za oko, otopina	not available	HR-H-904981713-01	NOVARTIS HRVATSKA D.O.O.	HR

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Tobrex 3 mg/ml oldatos szemcsepp	not available	OGYI-T-5294/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Tobrex 3 mg/g szemkenőcs	not available	OGYI-T-5295/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
TOBRAMICINA DOC Generici 3 mg/ml collirio, soluzione	not available	043324019	DOC GENERICI S.R.L.	IT
TOBRAMICINA EG "0,3% collirio, soluzione"	not available	042775015	EG S.P.A.	IT
Ursitan	ES/H/0190/001	042113011	LABORATORIOS SALVAT, S.A.	IT
Ursitan	ES/H/0190/001	042113023	LABORATORIOS SALVAT, S.A.	IT
Ursitan	ES/H/0190/001	042113035	LABORATORIOS SALVAT, S.A.	IT
MITOBRIN "0,3% collirio, soluzione"	not available	039812019	SOOFT ITALIA S.P.A.	IT
MITOBRIN "0,3% gocce auricolari, soluzione"	not available	039812045	SOOFT ITALIA S.P.A.	IT

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Ocupix 3mg/ml collirio, soluzione	not available	039571017	FARMIGEA SPA	IT
TIMORREB "0,3% collirio, soluzione"	not available	039811017	GENETIC SPA	IT
TIMORREB "0,3% gocce auricolari, soluzione"	not available	039811043	GENETIC SPA	IT
Tobrex LA 3 mg/ml akių lašai (tirpalas)	not available	LT/1/08/0966/001	SIA NOVARTIS BALTICS	LT
Tobrex 3 mg/g akių tepalas	not available	LT/1/92/0004/002	SIA "NOVARTIS BALTICS"	LT
Tobrex 3 mg/ml akių lašai (tirpalas)	not available	LT/1/92/0004/001	SIA "NOVARTIS BALTICS"	LT
TOBREX 3 mg/g acu ziede.	not available	05-0268	SIA "NOVARTIS BALTICS"	LV
TOBREX 3 mg/ml acu pilieni, šķīdums	not available	99-1060	SIA NOVARTIS BALTICS	LV
Tobrex® 3 mg/g eye ointment	not available	MA1249/02901	NOVARTIS IRELAND LIMITED	MT

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
Tobrex® 3 mg/mL eye drops, solution	not available	MA1249/02902	NOVARTIS IRELAND LIMITED	MT
TOBEX B.I.D. 3 mg/ml oogdruppels, oplossing	not available	RVG 28141	NOVARTIS PHARMA B.V.	NL
TOBEX oogzalf, 3 mg/g	not available	RVG 10225	NOVARTIS PHARMA B.V.	NL
Tobrex Depot 3 mg/ml depotøyedråper, oppløsning	not available	02-1292	NOVARTIS NORGE AS	NO
TOBEXAN, 3 mg/ml krople do oczu, roztwór	not available	14073	NOVARTIS POLAND SP. Z O. O.	PL
Tobrex, 3 mg/ml, krople do oczu, roztwór	not available	R/1894	NOVARTIS POLAND SP. Z O. O.	PL
Tobrex, 3 mg/g, maść do oczu.	not available	R/1875	NOVARTIS POLAND SP. Z O. O.	PL
Ursitan 0.75 mg/0.25 ml colírio, solução em recipiente unidose	ES/H/0190/001	5617931	LABORATORIOS SALVAT, S.A.	PT
Ursitan 0.75 mg/0.25 ml colírio, solução em recipiente unidose	ES/H/0190/001	5617949	LABORATORIOS SALVAT, S.A.	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
Ursitan 0.75 mg/0.25 ml colírio, solução em recipiente unidose	ES/H/0190/001	5617956	LABORATORIOS SALVAT, S.A.	PT
Tobrex 3 mg/g Pomada oftálmica	not available	8741017	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Tobrex 3 mg/ml Colírio, solução	not available	8740902	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
Tobrex 3 mg/ml picături oftalmice, soluție	not available	8412/2015/01	NOVARTIS PHARMA GMBH	RO
TOBREX 3 mg/g unguent oftalmic	not available	11113/2018/01	NOVARTIS PHARMA GMBH	RO
TOBREX 2X 3 mg/ml picături oftalmice, soluție	not available	8413/2015/01	NOVARTIS PHARMA GMBH	RO
Tobrex Depot 3 mg/ml ögondroppar, lösning	not available	18652	NOVARTIS SVERIGE AB	SE
TOBREX 3 mg/g mazilo za oko	not available	H/94/01533/001	NOVARTIS PHARMA GMBH	SI
TOBREX 3 mg/ml kapljice za oko, raztopina	not available	H/94/01533/002	NOVARTIS PHARMA GMBH	SI

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TOBREX očná masť	not available	64/0208/04-S	NOVARTIS SLOVAKIA S.R.O.	SK
TOBREX Očná roztoková instilácia 0,3 %	not available	64/0151/04-S	NOVARTIS SLOVAKIA S.R.O.	SK