



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

01 December 2016
EMA/848854/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Tobramycin (ophthalmic and otic use)

Procedure no.: PSUSA/00009317/201603



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 akiu lašai (tirpalas)	not available	LT/1/92/0004/001	SA ALCON-COUVREUR NV	LT
MITOBRIN “0,3% collirio, soluzione”	not available	039812019	SOOFT ITALIA S.P.A.	IT
TOBRAMICINA EG “0,3% collirio, soluzione”	not available	042775015	EG SPA	IT
Tobramaxin® Augentropfen	not available	1754.00.00	ALCON PHARMA GMBH	DE
TOBRAL 0,3% gocce auricolari, soluzione	not available	025860053	ALCON ITALIA S.P.A.	IT
TOBREX 0,3 %, pommade ophtalmique	not available	NL 13 545	LABORATOIRES ALCON S.A.S	FR
TOBREX 3 mg/g mast za oko	not available	HR-H-257802614	ALCON FARMACEUTIKA D.O.O.	HR
TOBREX 3 mg/ml kapi za oko, otopina	not available	HR-H-904981713	ALCON FARMACEUTIKA D.O.O.	HR
TOBRAVISC 3 mg/ml Augentropfen	not available	BE 264336	ALCON NV	BE

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TOBREX 3 mg/g Augensalbe	not available	BE125115	ALCON NV	BE
TOBREX 3 mg/ml Augentropfen	not available	BE125176	ALCON NV	BE
TOBREX 3 mg / g, pommade ophtalmique	not available	2005098234	ALCON NV	LU
ТОБРЕКС 3mg/ml капки за очи, разтвор	not available	II-0456	ALCON BULGARIA EOOD	BG
TOBREX 3 mg /ml, collyre en solution	not available	2005098233	ALCON NV	LU
TOBRAVISC 3 mg/ml collyre en solution	not available	2005040037	ALCON NV	LU
TOBRAVISC 0,3 % (3 mg/ml) ocná roztoková instilácia	not available	64/0714/09-S	ALCON CUSI, S.A	SK
TOBREX 2X 3 mg/ml picături oftalmice, soluție	not available	8413/2015/01	SA ALCON-COUVREUR NV	RO
Tobrex 3 mg/ml picături oftalmice, soluție	not available	8412/2015/01	SA ALCON-COUVREUR NV	RO

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TOBREX 3 mg/g oogzalf	not available	BE125115	ALCON NV	BE
TOBREX 3 mg/g pommade ophtalmique	not available	BE125115	ALCON NV	BE
TOBREX®-Augensalbe	not available	1-21066	ALCON OPHTHALMIKA GMBH	AT
ТОБРЕКС 3 mg/g маз за очи	not available	II-0455	ALCON BULGARIA EOOD	BG
TOBREX® Οφθαλμική αλοιφή 0,3%	not available	17321	A. POTAMITIS MEDICARE LTD	CY
Tobrex, 3 mg/g, maść do oczu	not available	R/1875	SA ALCON-COUVREUR NV	PL
TOBREX Οφθαλμική αλοιφή 0,3%	not available	47836	ALCON LABORATORIES HELLAS S.A.	GR
TOBRALâ 0,3% unguento oftalmico	not available	025860077	ALCON ITALIA S.P.A.	IT
TOBREX 3 mg/g mazilo za oko	not available	H/94/01533/001	SA ALCON-COUVREUR NV	SI

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TOBREX ocná mast	not available	64/0208/04-S	SA ALCON-COUVREUR NV	SK
TOBREX 3 mg/g unguent oftalmic	not available	7182/2006/01	SA ALCON-COUVREUR NV	RO
Tobramaxin® Augensalbe	not available	37896.00.00	ALCON PHARMA GMBH	DE
THILO-MICINE®	not available	43893/07/12-06-2008	PHARMEX S.A.	GR
Tobrex 3 mg/g szemkenőcs	not available	OGYI-T-5295/01	ALCON HUNGARIAN LTD.	HU
TOBREX 3 mg/g pommade ophtalmique	not available	2005098234	ALCON NV	LU
TOBREX 3 mg/g eye ointment	not available	MA015/00801	SA ALCON-COUVREUR NV	MT
TOBREX oogzalf, 3 mg/g	not available	RVG 10225	ALCON NEDERLAND BV	NL
TOBRAVISC 3 mg/ml collyre en solution	not available	BE264336	ALCON NV	BE

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THILO-MICINE®	not available	43891/07/12-06-2008	PHARMEX S.A.	GR
TOBREX 3 mg/ml oogdruppels, oplossing	not available	BE125176	ALCON NV	BE
TOBREX 3 mg/ml collyre en solution	not available	BE125176	ALCON NV	BE
TOBREX 3 mg/ml kapljice za oko, raztopina	not available	H/94/01533/002	SA ALCON-COUVREUR NV	SI
Tobrex 3 mg/ml oldatos szemcsepp	not available	OGYI-T-5294/01	ALCON HUNGARIAN LTD.	HU
TOBREX B.I.D. 3 mg/ml oogdruppels, oplossing	not available	RVG 28141	ALCON NEDERLAND BV	NL
TOBRALâ 0,3% collirio, soluzione	not available	025860026	ALCON ITALIA S.P.A.	IT
TOBREX® - Augentropfen	not available	1-19633	ALCON OPHTHALMIKA GMBH	AT
TOBREX 3 mg/ml collyre en solution	not available	2005098233	ALCON 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
TOBRAL 3mg/ml collirio a rilascio prolungato	not available	025860065	ALCON ITALIA S.P.A.	IT
TOBREX οφθαλμικές σταγόνες, διάλυμα 0,3%	not available	47835	ALCON LABORATORIES HELLAS S.A.	GR
TOBREX Očná roztoková instilácia 0,3 %	not available	64/0151/04-S	SA ALCON-COUVREUR NV	SK
TOBREX 3 mg/ml eye drops, solution	not available	MA015/00802	SA ALCON-COUVREUR NV	MT
TOBREXAN, 3 mg/ml krople do oczu, roztwór	not available	14073	SA ALCON-COUVREUR NV	PL
TOBREX®2x	not available	47838/14-10-2008	ALCON LABORATORIES HELLAS S.A.	GR
TOBREX®2X	not available	19595	A. POTAMITIS MEDICARE LTD	CY
TOBRAVISC 3 mg/ml collyre en solution	not available	2005040037	ALCON NV	LU
Tobrex, 3 mg/ml, krople do oczu, roztwór	not available	R/1894	SA ALCON-COUVREUR NV	PL

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® Οφθαλμικές σταγόνες, διάλυμα 0,3%	not available	17322	A. POTAMITIS MEDICARE LTD	CY
TOBRAVISC 3 mg/ml oogdruppels, oplossing	not available	BE 264336	ALCON NV	BE
Tobrex, 3 mg/g silmasalv	not available	353301	SA ALCON-COUVREUR NV	EE
Ursitan 3 mg/ml colirio en solución en envase unidosis	ES/H/0190/001	77752	LABORATORIOS SALVAT, S.A.	ES
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
Ursitan 3 mg/ml colírio, solução em recipiente unidose	ES/H/0190/001	5617931	LABORATORIOS SALVAT, S.A.	PT
Ursitan 3 mg/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 3 mg/ml colírio, solução em recipiente unidose	ES/H/0190/001	5617956	LABORATORIOS SALVAT, S.A.	PT
Tobrex Depot 3 mg/ml silmätipat, liuos	not available	17507	ALCON CUSI, S.A	FI
Tobrex Depot 3 mg/ml ögondroppar, lösning	not available	18652	ALCON CUSI, S.A	SE
TOBREX 2x, 3 mg/ml silmatilgad, lahus	not available	459305	ALCON CUSI, S.A	EE
TOBRAVISC, 3.0 mg/ml eye drops, solution	not available	PL 00649/0172	ALCON LABORATORIES (UK) LTD	UK
TIMORREB 0,3% collirio, soluzione	not available	039811017	GENETIC SPA	IT
TIMORREB 0,3% gocce auricolari, soluzione	not available	039811043	GENETIC SPA	IT
TOBREX® UNGÜENTO OFTÁLMICO 3 mg/g pomada oftálmica	not available	57.593	ALCON CUSI, S.A	ES
Tobrex Depot, depotøjendråber, opløsning	not available	33984	ALCON CUSI, S.A	DK

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 colirio en solución	not available	57.594	ALCON CUSI, S.A	ES
TOBREX 3 mg/g akių tepalas	not available	LT/1/92/0004/002	SA ALCON-COUVREUR NV	LT
Tobrex Depot 3 mg/ml depotøyedråper, oppløsning	not available	02-1292	ALCON CUSI, S.A	NO
TOBREX 3 mg/ml acu pilieni, šķīdums	not available	99-1060	SA ALCON-COUVREUR NV	LV
TOBREXAN 3 mg/ml Colírio, solução	not available	4742185	ALCON PORTUGAL - PRODUTOS E EQUIPAMENTOS OFTALMOLÓGICOS, LDA.	PT
Tobrex 3 mg/g Pomada oftálmica	not available	8741017	ALCON PORTUGAL - PRODUTOS E EQUIPAMENTOS OFTALMOLÓGICOS, LDA.	PT
TOBREX 3 mg/g acu ziede	not available	05-0268	SA ALCON-COUVREUR NV	LV
TOBREX, oční kapky, roztok	not available	64/106/87-C	SA ALCON-COUVREUR NV	CZ
TOBREX LA oční kapky, roztok	not available	64/257/05-C	ALCON CUSI, S.A	CZ

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Tobrex 3 mg/ml Colírio, solução	not available	8740902	ALCON PORTUGAL - PRODUTOS E EQUIPAMENTOS OFTALMOLÓGICOS, LDA.	PT
ROCOTOB “0,3% gocce auricolari, soluzione”	not available	042688046	LABORATORIO CHIMICO DECA DR. CAPUANI S.R.L.	IT
ROCOTOB “0,3% gocce auricolari, soluzione”	not available	042688034	LABORATORIO CHIMICO DECA DR. CAPUANI S.R.L.	IT
TOBREX 0,3 %, collyre en solution	not available	NL 13 546	LABORATOIRES ALCON S.A.S	FR
TOBREXAN 3 mg/ml colirio en solución	not available	66.421	ALCON CUSI, S.A	ES
TOBREX LA 3 mg/ml akių lašai (tirpalas)	not available	LT/1/08/0966/001	ALCON CUSI, S.A	LT
OCUPIX “0,3% Collirio, soluzione”	not available	039571017	FARMIGEA SPA	IT
TOBREX L.P. 3 mg/ml collyre en solution	not available	NL 27942	LABORATOIRES ALCON S.A.S	FR
TOBREX, oční mast	not available	64/128/91-C	SA ALCON-COUVREUR NV	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
TOBRAMICINA DOC Generici 3 mg/ml collirio, soluzione	not available	043324019	DOC GENERICI S.R.L.	IT