

Amsterdam, 20 December 2021  
EMA/772643/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: dexamethasone / tobramycin (ophtalmic and otic use)

Procedure no.: PSUSA/00000979/202103

<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Mybracin, (3 mg + 1 mg)/ml, krople do oczu, zawiesina	not available	21342	ADAMED PHARMA S.A.	PL
TOBRADEX 0,1% w/v + 0,3% w/v, οφθαλμικές σταγόνες, εναιώρημα	not available	199920101	NOVARTIS (HELLAS) S.A.C.I.	GR
TOBRADEX očná suspenzná instilácia	not available	64/0219/04-S	NOVARTIS SLOVAKIA S.R.O.	SK
TOBRADEX, collyre en suspension	not available	3400934429972	NOVARTIS PHARMA S.A.S.	FR
TOBRADEX 3mg/ml/1mg/ml Eye Drops, Suspension	FI/H/0981/001	PL 00101/1007	NOVARTIS PHARMACEUTICALS UK LIMITED	XI
TOBRADEX 3mg/ml / 1mg/ml Augentropfensuspension	FI/H/0981/001	62856.00.00	NOVARTIS PHARMA GMBH	DE
Tobradex, øjendråber, suspension	FI/H/0981/001	37948	NOVARTIS HEALTHCARE A/S	DK

Tobrasone 3 mg/ml + 1 mg/ml - silmätipat, suspensio	FI/H/0981/001	21022	NOVARTIS FINLAND OY	FI
Tobrasone 3 mg/ml/1 mg/ml ögondroppar, suspension	FI/H/0981/001	21022	NOVARTIS FINLAND OY	FI
Tobradex 3 mg/ml/1 mg/ml augndropar, dreifa	FI/H/0981/001	IS/1/05/029/01	NOVARTIS HEALTHCARE A/S	IS
Tobrasone 3 mg/ml / 1 mg/ml, øyedråper, suspensjon	FI/H/0981/001	05-3429	NOVARTIS NORGE AS	NO
Tobrasone 3 mg/ml / 1 mg/ml ögondroppar, suspension	FI/H/0981/001	22413	NOVARTIS SVERIGE AB	SE
Tobradex 3 mg/ml + 1 mg/ml colírio, suspensão	FI/H/0981/001	5572383	NOVARTIS FARMA - PRODUTOS FARMACÊUTICOS S.A.	PT
COLDETOM 0,3% + 0,1% gocce auricolari, soluzione	not available	042542035	SCHARPER SPA	IT
TOBRADEX 0,1% w/w + 0,3% w/w, οφθαλμική αλοιφή	not available	199920201	NOVARTIS (HELLAS) S.A.C.I.	GR

Tobradex 3 mg + 1 mg/ml kapi za oko, suspenzija	not available	HR-H-813846689-01	NOVARTIS HRVATSKA D.O.O.	HR
TOBRADEX®, Eye Drops, Suspension	not available	MA1249/02801	NOVARTIS IRELAND LIMITED	MT
TOBRADEX®, Eye Ointment	not available	MA1249/02802	NOVARTIS IRELAND LIMITED	MT
TOBRADEX 3 mg/g + 1 mg/g oogzalf	not available	BE144724	NOVARTIS PHARMA N.V.	BE
TOBRADEX 3 mg/ml + 1 mg/ml oogdruppels, suspensie	not available	BE144873	NOVARTIS PHARMA N.V.	BE
TOBRADEX 3 mg/g + 1 mg/g pommade ophtalmique	not available	BE144724	NOVARTIS PHARMA N.V.	BE
TOBRADEX 3 mg/ml + 1 mg/ml collyre en suspension	not available	BE144873	NOVARTIS PHARMA N.V.	BE
TOBRADEX 3 mg/g + 1 mg/g Augensalbe	not available	BE144724	NOVARTIS PHARMA N.V.	BE

TOBRADEX, 3 mg/ml + 1 mg/ml Augentropfsuspension	not available	BE144873	NOVARTIS PHARMA N.V.	BE
TOBRADEX® Augentropfen	not available	1-22591	NOVARTIS PHARMA GMBH	AT
TOBRADEX® Augensalbe	not available	1-22590	NOVARTIS PHARMA GMBH	AT
Tobradex 1mg + 3mg/g unguent oftalmic	not available	8967/2016/01	NOVARTIS PHARMA GMBH	RO
Tobramicina Desametasone Bausch & Lomb 3 mg/ml + 1 mg/ml collirio, sospensione	SE/H/0745/001	040276014	BAUSCH & LOMB IOM S.P.A	IT
Detobra 1 mg/ml+3 mg/ml collyre en suspension	not available	BE500151	MYLAN EPD BVBA/SPRL	BE
Detobra 1 mg/ml+3 mg/ml oogdruppels, suspensie	not available	BE500151	MYLAN EPD BVBA/SPRL	BE
Detobra 1 mg/ml+3 mg/ml Augentropfen, Suspension	not available	BE500151	MYLAN EPD BVBA/SPRL	BE

Detobra 1 mg/ml+3 mg/ml Augentropfen, Suspension	not available	2017040079	MYLAN EPD BVBA/SPRL	LU
Detobra 1 mg/ml+3 mg/ml collyre en suspension	not available	2017040079	MYLAN EPD BVBA/SPRL	LU
TOBRADEX 3 mg/g + 1 mg/g oční mast	not available	64/170/06-C	NOVARTIS S.R.O.,	CZ
TOBRADEX 0,1% w/v + 0,3% w/v, οφθαλμικές σταγόνες, εναιώρημα	not available	17319	NOVARTIS IRELAND LIMITED	CY
TOBRADEX 0,1% w/w + 0,3% w/w, οφθαλμική αλοιφή	not available	17323	NOVARTIS IRELAND LIMITED	CY
Tobradex 3 mg/ml + 1 mg/ml oogdruppels, suspensie	not available	RVG 14223	NOVARTIS PHARMA B.V.	NL
Tobradex 3 mg/g + 1 mg/g oogzalf	not available	RVG 14224	NOVARTIS PHARMA B.V.	NL
Tobramycin/Dexamethasone Ingen Pharma 3 mg/1 mg/ml akių lašai (suspensija)	not available	LT/1/18/4224/001	SIA INGEN PHARMA	LT

ТОБРАДЕКС 3 mg/ 1 mg/ml капки за очи, суспензия	not available	9600064	NOVARTIS PHARMA GMBH	BG
Tobradex 1mg + 3mg/ml picaturi oftalmice, suspensie	not available	8966/2016/01	NOVARTIS PHARMA GMBH	RO
COLDETOM 0,3% + 0,1% gocce auricolari, soluzione	not available	042542047	SCHARPER SPA	IT
Visucombidex 0,3% + 0,1% collirio, soluzione	not available	039899024	VISUFARMA SPA	IT
COMBITIMOR 0,3% + 0,1% gocce auricolari, soluzione	not available	040347039	SOOFT ITALIA S.P.A.	IT
COMBITIMOR 0,3% + 0,1% gocce auricolari, soluzione	not available	040347041	SOOFT ITALIA S.P.A.	IT
COMBITIMOR 0,3% + 0,1% collirio, soluzione	not available	040347015	SOOFT ITALIA S.P.A.	IT
COMBITIMOR 0,3% + 0,1% collirio, soluzione	not available	040347027	SOOFT ITALIA S.P.A.	IT

COMBISTILL 0,3% + 0,1% collirio, sospensione	not available	041033010	BRUSCHETTINI S.R.L	IT
TOBRADEX 1 mg/3 mg v 1 g mazilo za oko	not available	H/99/01532/001	NOVARTIS PHARMA GMBH	SI
TOBRADEX 1 mg/3 mg v 1 ml kapljice za oko, suspenzija	not available	H/99/01532/002	NOVARTIS PHARMA GMBH	SI
Luxabiotic 3 mg/ml + 1 mg/ml collirio, sospensione	IT/H/0420/001	040918017	OMNIVISION ITALIA S.R.L.	IT
TODEXAL 3 mg/1 mg par ml, collyre en suspension	not available	34009 301 515 0 1	LABORATOIRES DOLIAGE DEVELOPPEMENT	FR
Tobradex 3 mg/1 mg/ml akių lašai (suspensija)	not available	LT/1/2000/1352/001	SIA NOVARTIS BALTICS	LT
TOBRAMICINA E DESAMETASONE DOC Generici 3 mg/ml + 1 mg/ml collirio, soluzione	not available	043354012	DOC GENERICI S.R.L.	IT
Oridecin 3 mg/ml + 1 mg/ml ögonddroppar, suspension	DK/H/2922/001	57947	ORIFARM GENERICS A/S	SE



Oridecin, øjendråber, suspension	DK/H/2922/001	61236	ORIFARM GENERICS A/S	DK
Toflacort 3 mg/ml + 1 mg/ml ögondroppar, suspension	SE/H/0745/001	43071	BLUMONT OFTA TRADING LIMITED	SE
TOBRADEX očná masť	not available	64/0218/04-S	NOVARTIS SLOVAKIA S.R.O.	SK
Tobradex 3 mg + 1 mg/g mast za oko	not available	HR-H-942799697-01	NOVARTIS HRVATSKA D.O.O.	HR
Tobradex 3 mg/g / 1 mg/g acu ziede	not available	01-0317	SIA "NOVARTIS BALTICS"	LV
Tobradex 3 mg/1 mg/ml acu pilieni, suspensija	not available	99-1058	SIA NOVARTIS BALTICS	LV
VARDAMIR 0,3% + 0,1% collirio, soluzione	not available	042537011	OMIKRON ITALIA S.R.L.	IT
VARDAMIR 0,3% + 0,1% collirio, soluzione	not available	042537023	OMIKRON ITALIA S.R.L.	IT

Bradexa 3 mg/ml + 1 mg/ml oogdruppels, suspensie	not available	RVG 123316	ROCKMED PHARMA B.V.	NL
TOBRAMICINA E DESAMETASONE EG 0,3% + 0,1% collirio, soluzione	not available	042778011	EG S.P.A.	IT
Tobradex 3 mg/1 mg/ml, silmatilgad, suspensioon	not available	199998	SIA NOVARTIS BALTICS	EE
Tobradex 3 mg/g / 1 mg/g silmasalv	not available	466805	SIA "NOVARTIS BALTICS"	EE
Tobradex, (3 mg + 1 mg)/ml, krople do oczu, zawiesina	not available	9417	NOVARTIS POLAND SP. Z O. O.	PL
ТОБРАДЕКС 3 mg/ 1 mg/g маз за очи	not available	9600065	NOVARTIS PHARMA GMBH	BG
TOBRADEX szemkenőcs	not available	OGYI-T-1942/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Tobradex szuszpenziós szemcsepp	not available	OGYI-T-1941/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU

TobraDex 0,3% + 0,1% unguento oftalmico	not available	027457023	NOVARTIS FARMA S.P.A.	IT
TobraDex 0,3% + 0,1% gocce auricolari, sospensione	not available	027457035	NOVARTIS FARMA S.P.A.	IT
TobraDex 0,3% + 0,1% collirio, sospensione	not available	027457011	NOVARTIS FARMA S.P.A.	IT
TOBRADEX 3 mg/ml + 1 mg/ml oční kapky, suspenze	not available	64/706/99-C	NOVARTIS S.R.O.,	CZ
TodEP szuszpenziós szemcsepp	not available	OGYI-T-22899/01	EXTRACTUMPHARMA CO.LTD.	HU
Visucombidex 0,3% + 0,1% collirio, soluzione	not available	039899012	VISUFARMA SPA	IT