



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

02 September 2021
EMA/467432/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tobramycin (nebuliser solution) (apart from centrally authorised product)

Procedure no.: PSUSA/00009316/202012

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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
Bramitob 300 mg/4 ml Lösung für einen Vernebler	IT/H/0132/001	1-26797	CHIESI PHARMACEUTICALS GMBH	AT
TOBI 300 mg/5 mL - Lösung für einen Vernebler	NL/H/4274/001	1-23973	MYLAN ÖSTERREICH GMBH	AT
Tobramycin Aristo 300 mg/5 ml Lösung für einen Vernebler	NL/H/4192/001	138828	ARISTO PHARMA GMBH (ART 57)	AT
TOBI 300 mg/5 ml verneveloplossing	NL/H/4274/001	BE219676	MYLAN EPD BVBA/SPRL	BE
TOBI 300 mg/5 ml Solution pour Inhalation par Nébuliseur	NL/H/4274/001	BE219676	MYLAN EPD BVBA/SPRL	BE
TOBI 300 mg/5 ml Lösung für einen Vernebler	NL/H/4274/001	BE219676	MYLAN EPD BVBA/SPRL	BE
Тобрамицин Виа фарма 300 mg/5 ml разтвор за небулизатор	LT/H/0112/001	20160288	UAB VIA PHARMA	BG
TOBI 300 mg/ 5 ml Διάλυμα για εισπνοή με εκνεφωτή	not available	19439	MYLAN IRE HEALTHCARE LIMITED	CY
BRAMITOB 300 mg/ 4 ml, roztok k rozprašování	IT/H/0132/001	15/214/07-C	CHIESI PHARMACEUTICALS GMBH	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
TOBI Nebuliser Solution 300 mg/5 ml roztok k rozprašování	not available	15/312/03-C	MYLAN IRE HEALTHCARE LIMITED	CZ
BRAMITOB® 300 mg/4 ml Lösung für einen Vernebler	IT/H/0132/001	65777.00.00	CHIESI GMBH	DE
Tobramycin Zentiva 300 mg / 5 ml Lösung für einen Vernebler	ES/H/0728/001	2199283.00.00	ZENTIVA PHARMA GMBH	DE
Tobramycin Teva 300 mg/5 ml Steri-Neb Lösung für einen Vernebler	NL/H/4711/001	81406.00.00	TEVA GMBH	DE
Tobramycin Zentiva 300 mg / 5 ml Lösung für einen Vernebler	ES/H/0728/001	2199283.00.00	ZENTIVA PHARMA GMBH	DE
TOBI 300 mg/5 ml Lösung für einen Vernebler	NL/H/4274/001	49612.00.00	MYLAN HEALTHCARE GMBH	DE
Tobramycin SUN 300 mg Lösung für einen Vernebler	NL/H/3560/001	95878.00.00	SUN PHARMACEUTICALS GERMANY GMBH	DE
Tobramycin Aristo 300 mg/5 ml Lösung für einen Vernebler	NL/H/4192/001	2201030.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Tobramycin "Teva", inhalationsvæske til nebulisator, opløsning	NL/H/4711/001	46486	TEVA B.V	DK

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Tobi, inhalationsvæske til nebulisator, opløsning	NL/H/4274/001	31533	MYLAN DENMARK APS	DK
Tobramycin "SUN", inhalationsvæske til nebulisator, opløsning	NL/H/3560/001	56567	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	DK
Tobramycin Via pharma 300 mg/5 ml nebuliseeritav lahus	LT/H/0112/001	911916	UAB VIA PHARMA	EE
BRAMITOB 300 mg/4 ml Solución para inhalación por nebulizador	IT/H/0132/001	68621	CHIESI ESPAÑA S.A.U.	ES
Tobramicina Accord 300 mg/5 ml solución para inhalación por nebulizador	PT/H/0504/001	75344	ACCORD HEALTHCARE S.L.U.	ES
Tobramicina Teva 300 mg/5 ml solución para inhalación por nebulizador	NL/H/4711/001	75612	TEVA PHARMA S.L.U.,	ES
Tobramicina Altan 300 mg/5 ml solución para inhalación por nebulizador	ES/H/0728/001	84187	ALTAN PHARMACEUTICALS S.A.	ES
TOBI 300 mg/5 ml solución para inhalación por nebulizador	NL/H/4274/001	63.689	MYLAN IRE HEALTHCARE LIMITED	ES
Tobramicina SUN 300 mg/5 ml solución para inhalación por nebulizador	NL/H/3560/001	82287	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES

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TOBI 300 mg/5 ml sumutinliuos	NL/H/4274/001	15744	MYLAN FINLAND OY	FI
Tobi 300 mg/5 ml lösning för nebulisator	NL/H/4274/001	15744	MYLAN FINLAND OY	FI
TOBRAMYCINE ZENTIVA 300 mg/5 mL, solution pour inhalation par nébuliseur	ES/H/0728/001	34009 301 777 3 0	ZENTIVA FRANCE	FR
TOBRAMYCINE ZENTIVA 300 mg/5 mL, solution pour inhalation par nébuliseur	ES/H/0728/001	34009 550 647 6 3	ZENTIVA FRANCE	FR
TOBRAMYCINE ZENTIVA 300 mg/5 mL, solution pour inhalation par nébuliseur	ES/H/0728/001	34009 550 647 8 7	ZENTIVA FRANCE	FR
TOBRAMYCINE ZENTIVA 300 mg/5 mL, solution pour inhalation par nébuliseur	ES/H/0728/001	34009 301 777 3 0	ZENTIVA FRANCE	FR
TOBRAMYCINE ZENTIVA 300 mg/5 mL, solution pour inhalation par nébuliseur	ES/H/0728/001	34009 550 647 6 3	ZENTIVA FRANCE	FR
TOBRAMYCINE ZENTIVA 300 mg/5 mL, solution pour inhalation par	ES/H/0728/001	34009 550 647 8 7	ZENTIVA FRANCE	FR

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nébuliseur				
TOBI 300 mg / 5 ml, solution pour inhalation par nébuliseur	NL/H/4274/001	3400936572324	MYLAN MEDICAL SAS	FR
TOBI 300 mg / 5 ml, solution pour inhalation par nébuliseur	NL/H/4274/001	3400938071863	MYLAN MEDICAL SAS	FR
TOBI 300 mg / 5 ml, solution pour inhalation par nébuliseur	NL/H/4274/001	3400938071924	MYLAN MEDICAL SAS	FR
TOBRAMYCINE SUN 300 mg/5 mL, solution pour inhalation par nébuliseur	NL/H/3560/001	34009 301 630 7 8	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
TOBRAMYCINE SUN 300 mg/5 mL, solution pour inhalation par nébuliseur	NL/H/3560/001	34009 550 599 1 2	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
TOBRAMYCINE SUN 300 mg/5 mL, solution pour inhalation par nébuliseur	NL/H/3560/001	34009 550 599 0 5	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	FR
BRAMITOB 300 mg/ 4 ml Διάλυμα για εισπνοή με εκνεφωτή.	IT/H/0132/001	2721101	CHIESI HELLAS S.A.	GR
TOBI® 300 mg/5 ml Διάλυμα για εισπνοή με εκνεφωτή	NL/H/4274/001	28937/18-04-2011	MYLAN IRE HEALTHCARE LIMITED	GR

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
BRAMITOB 300 mg/4 ml otopina za nebulizator	not available	HR-H-873495110	CHIESI PHARMACEUTICALS GMBH	HR
Bramitob 300 mg /4 ml oldat porlasztásra	IT/H/0132/001	OGYI-T-20 324/04	CHIESI PHARMACEUTICALS GMBH	HU
Bramitob 300 mg /4 ml oldat porlasztásra	IT/H/0132/001	OGYI-T-20 324/01	CHIESI PHARMACEUTICALS GMBH	HU
Bramitob 300 mg /4 ml oldat porlasztásra	IT/H/0132/001	OGYI-T-20 324/02	CHIESI PHARMACEUTICALS GMBH	HU
Bramitob 300 mg /4 ml oldat porlasztásra	IT/H/0132/001	OGYI-T-20 324/03	CHIESI PHARMACEUTICALS GMBH	HU
Tobramycin Via pharma 300 mg/ 5 ml oldat porlasztásra	LT/H/0112/001	OGYI-T-23038/01	UAB VIA PHARMA	HU
Bramitob 300mg/4ml Nebuliser Solution	IT/H/0132/001	PA0584/007/001	CHIESI FARMACEUTICI S.P.A.	IE
Tymbrineb 300 mg/5 ml Nebuliser Solution	NL/H/4711/001	PA0749/117/001	TEVA PHARMA B.V.	IE
TOBI 300 mg/5 mL Nebuliser Solution	NL/H/4274/001	PA2010/063/001	MYLAN IRE HEALTHCARE LIMITED	IE

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
BRAMITOB 300 mg/4 ml soluzione da nebulizzare	not available	036646014	CHIESI FARMACEUTICI S.P.A.	IT
BRAMITOB 300 mg/4 ml soluzione da nebulizzare	not available	036646026	CHIESI FARMACEUTICI S.P.A.	IT
BRAMITOB 300 mg/4 ml soluzione da nebulizzare	not available	036646038	CHIESI FARMACEUTICI S.P.A.	IT
Tobramicina Teva 300 mg / 5 ml Soluzione per nebulizzatore	NL/H/4711/001	041632011	TEVA ITALIA S.R.L.	IT
Tobramicina Teva 300 mg / 5 ml Soluzione per nebulizzatore	NL/H/4711/001	041632023	TEVA ITALIA S.R.L.	IT
Tobramicina Teva 300 mg / 5 ml Soluzione per nebulizzatore	NL/H/4711/001	041632035	TEVA ITALIA S.R.L.	IT
TOBI 300 mg/5 ml soluzione per nebulizzatore	NL/H/4274/001	034767018	MYLAN IRE HEALTHCARE LIMITED	IT
Tobramicina SUN 300 mg/5 ml soluzione per nebulizzatore	NL/H/3560/001	044611022	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Tobramicina SUN 300 mg/5 ml soluzione per nebulizzatore	NL/H/3560/001	044611010	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT

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 SUN 300 mg/5 ml soluzione per nebulizzatore	NL/H/3560/001	044611034	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Tobramicina Aristo 300 mg/5 ml soluzione per nebulizzatore	NL/H/4192/001	046040010	ARISTO PHARMA GMBH (ART 57)	IT
Bramitob 300 mg/4 ml purškiamasis įkvepiamasis tirpalas	not available	LT/1/11/2643/004	CHIESI PHARMACEUTICALS GMBH	LT
Tobramycin Via pharma 300 mg/5 ml purškiamasis įkvepiamasis tirpalas	LT/H/0112/001	LT/1/16/3931/001	UAB VIA PHARMA	LT
TOBI 300 mg/5 ml, solution pour inhalation par nébuliseur	NL/H/4274/001	2000/11/00/32	MYLAN EPD BVBA/SPRL	LU
TOBI 300 mg/5 ml Lösung für einen Vernebler	NL/H/4274/001	2000/11/00/32	MYLAN EPD BVBA/SPRL	LU
BRAMITOB 300 mg/4 ml šķīdums izsmidzināšanai	not available	11-0276	CHIESI PHARMACEUTICALS GMBH	LV
Tobramycin Via pharma 300 mg/5 ml šķīdums izsmidzināšanai	LT/H/0112/001	16-0100	UAB VIA PHARMA	LV
TOBI 300 mg/5 mL Nebuliser Solution	NL/H/4274/001	MA 1187/03801	MYLAN IRE HEALTHCARE 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
BRAMITOB, verneveloplossing 300 mg/4 ml	IT/H/0132/001	RVG 33841	CHIESI PHARMACEUTICALS B.V.	NL
Tobramycine Steri-Neb 300 mg/5 ml, verneveloplossing	NL/H/4711/001	RVG 106999	TEVA NEDERLAND B.V.	NL
TOBI 300 mg/5 ml verneveloplossing	NL/H/4274/001	RVG 25484	MYLAN HEALTHCARE B.V.	NL
Tobramycine SUN 300 mg/5 ml verneveloplossing	NL/H/3560/001	RVG 117965	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Tobramycine Aristo 300mg/ 5ml verneveloplossing	NL/H/4192/001	RVG 121938	ARISTO PHARMA GMBH (ART 57)	NL
TOBI 300 mg/5 ml inhalasjonsvæske til nebulisator, oppløsning	NL/H/4274/001	00-2577	MYLAN HEALTHCARE NORGE AS	NO
Bramitob, 300 mg/4 ml, roztwór do nebulizacji	IT/H/0132/001	12796	CHIESI FARMACEUTICI S.P.A.	PL
Tobramycin Via pharma, 300 mg/5 ml, roztwór do nebulizacji	LT/H/0112/001	23633	UAB VIA PHARMA	PL
Tobramycyna SUN, 300 mg/5 mL, roztwór do nebulizacji	NL/H/3560/001	23837	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	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
Bramitob 300 mg/4 ml Solução para inalação por nebulização	IT/H/0132/001	5043955	CHIESI FARMACEUTICI S.P.A.	PT
Tobramicina Medichem, 300 mg/5 ml, Solução para inalação por nebulização	PT/H/0934/001	PT/H/0934/01	MEDICHEM, S.A.	PT
Tobramicina Accord 300 mg/5 ml Solução para Inalação por Nebulização	PT/H/0504/001	5455860	ACCORD HEALTHCARE S.L.U.	PT
Tobramicina Teva, 300 mg/5 ml, Solução para Inalação por Nebulização	NL/H/4711/001	5552716	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Tobramicina Altan 300 mg/5 ml Solução para inalação por nebulização	ES/H/0728/001	5773239	ALTAN PHARMACEUTICALS S.A.	PT
Tobramicina Altan 300 mg/5 ml Solução para inalação por nebulização	ES/H/0728/001	5773254	ALTAN PHARMACEUTICALS S.A.	PT
Tobramicina Altan 300 mg/5 ml Solução para inalação por nebulização	ES/H/0728/001	5773247	ALTAN PHARMACEUTICALS S.A.	PT
Tobramicina Medichem, 300 mg/5 ml, Solução para inalação por nebulização	PT/H/0934/001	PT/H/0934/01	MEDICHEM, S.A.	PT
TOBI 300 mg/5 ml, Solução para Inalação por Nebulização	NL/H/4274/001	3424389	BGP PRODUCTS UNIPESOOAL, LDA.	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
Tobramycin Via pharma 300 mg/5 ml soluție pentru inhalare prin nebulizator	LT/H/0112/001	9235/2016/01	UAB VIA PHARMA	RO
TOBI 300 mg/5 ml soluție pentru inhalare prin nebulizator	not available	8377/2015/02	MYLAN IRE HEALTHCARE LIMITED	RO
TOBI 300 mg/5 ml soluție pentru inhalare prin nebulizator	not available	8377/2015/01	MYLAN IRE HEALTHCARE LIMITED	RO
TOBI 300 mg/5 ml soluție pentru inhalare prin nebulizator	not available	8377/2015/03	MYLAN IRE HEALTHCARE LIMITED	RO
Tobramicină SUN 300 mg soluție pentru nebulizator	NL/H/3560/001	9993/2017/01	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Tobramicină SUN 300 mg soluție pentru nebulizator	NL/H/3560/001	9993/2017/03	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
Tobramicină SUN 300 mg soluție pentru nebulizator	NL/H/3560/001	9993/2017/02	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
TOBI 300 mg/5 ml, lösning för nebulisator	NL/H/4274/001	16319	BGP PRODUCTS AB	SE
Bramitob 300 mg/4 ml roztok na rozprašovanie	IT/H/0132/001	15/0534/06-S	CHIESI PHARMACEUTICALS GMBH	SK

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
Bramitob 300 mg/4ml Nebuliser Solution	IT/H/0132/001	PL 8829/0155	CHIESI LIMITED	XI
Tobramycin 300 mg/5 ml Nebuliser Solution	PT/H/0934/001	PL 31862/0050	CREO PHARMA LTD	XI
Tobramycin 300 mg/5 ml Nebuliser Solution	NL/H/4711/001	PL 00289/1437	TEVA UK LIMITED	XI
Tobramycin 300 mg/5 ml Nebuliser Solution	PT/H/0934/001	PL 31862/0050	CREO PHARMA LTD	XI
Tobramycin Altan 300 mg/5 ml Nebuliser solution	ES/H/0728/001	PL 46788/0003	ALTAN PHARMA LTD	XI
TOBI 300 mg/5 mL Nebuliser Solution	NL/H/4274/001	PL 46302/0205	MYLAN PRODUCTS LIMITED	XI
Munuza 300 mg/5 ml nebuliser solution	NL/H/4192/001	PL 40546/0068	ARISTO PHARMA GMBH (ART 57)	XI