



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 September 2018  
EMA/615391/2018  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00009316/201712



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 300 mg/5 ml, solution pour inhalation par nébuliseur	NL/H/4274/001	2000/11/00/32	NOVARTIS PHARMA N.V.	LU
TOBI® 300 mg/5 ml Lösung für einen Vernebler	NL/H/4274/001	2000/11/00/32	NOVARTIS PHARMA N.V.	LU
TOBI® 300 mg/5 ml Lösung für einen Vernebler	NL/H/4274/001	BE219676	NOVARTIS PHARMA N.V.	BE
Tobi	NL/H/4274/001	31533	NOVARTIS HEALTHCARE A/S	DK
Tobi 300 mg/5 ml solução para inalação por nebulização	NL/H/4274/001	3424389	NOVARTIS FARMA - PRODUTOS FARMACÉUTICOS S.A.	PT
TOBI 300 mg/5 ml solución para inhalación por nebulizador	NL/H/4274/001	63.689	NOVARTIS FARMACÉUTICA S.A.	ES
Tobi 300 mg/5 ml soluzione da nebulizzare	NL/H/4274/001	034767018	NOVARTIS EUROPHARM LIMITED	IT
TOBI 300 mg/5 ml sumutinliuos	NL/H/4274/001	15744	NOVARTIS FINLAND OY	FI
TOBI 300 mg/5 ml lösning för nebulisator	NL/H/4274/001	15744	NOVARTIS FINLAND OY	FI
TOBI® 300 mg/5 ml Διάλυμα για εισπνοή με εκνεφωτή	NL/H/4274/001	248950101	NOVARTIS (HELLAS) S.A.C.I.	GR
TOBI® 300 mg/5 ml Διάλυμα για εισπνοή με εκνεφωτή	NL/H/4274/001	248950102	NOVARTIS (HELLAS) S.A.C.I.	GR
TOBI® 300 mg/5 ml Διάλυμα για εισπνοή με εκνεφωτή	NL/H/4274/001	248950103	NOVARTIS (HELLAS) S.A.C.I.	GR
Tobi 300 mg/5 ml oldat porlasztásra	not available	OGYI-T-8707/01	NOVARTIS HUNGÁRIA KFT. PHARMA	HU

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Tobi 300 mg/5 ml oldat porlasztásra	not available	OGYI-T-8707/02	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Tobi 300 mg/5 ml oldat porlasztásra	not available	OGYI-T-8707/03	NOVARTIS HUNGÁRIA KFT. PHARMA	HU
Tobi 300 mg/5 ml - Lösung für einen Vernebler	NL/H/4274/001	1-23973	NOVARTIS PHARMA GMBH	AT
TOBI 300 mg/5 ml inhalasjonsvæske til nebulisator, oppløsning	NL/H/4274/001	00-2577	NOVARTIS NORGE AS	NO
TOBI® 300 mg/5 ml Lösung für einen Vernebler	NL/H/4274/001	49612.00.00	NOVARTIS PHARMA GMBH	DE
TOBI 300 mg/5 ml nebuliser solution/ ТОБИ 300mg/5ml разтвор за пулверизиране	not available	20050096	NOVARTIS PHARMA GMBH	BG
TOBI 300 mg/5 ml verneveloplossing	NL/H/4274/001	BE219676	NOVARTIS PHARMA N.V.	BE
Tobi 300 mg/5 ml verneveloplossing	NL/H/4274/001	RVG 25484	NOVARTIS PHARMA B.V.	NL
TOBI 300 mg/5 ml, solution pour inhalation par nébuliseur	NL/H/4274/001	BE219676	NOVARTIS PHARMA N.V.	BE
TOBI 300 mg/5 ml soluție pentru inhalare prin nebulizator	not available	8377/2015/01	NOVARTIS PHARMA GMBH	RO
TOBI 300 mg/5 ml soluție pentru inhalare prin nebulizator	not available	8377/2015/02	NOVARTIS PHARMA GMBH	RO
TOBI 300 mg/5 ml soluție pentru inhalare prin nebulizator	not available	8377/2015/03	NOVARTIS PHARMA GMBH	RO

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Tobi 300mg/5ml,solution pour inhalation par nébuliseur	NL/H/4274/001	3400936572324	NOVARTIS PHARMA S.A.S.	FR
Tobi 300mg/5ml,solution pour inhalation par nébuliseur	NL/H/4274/001	3400938071863	NOVARTIS PHARMA S.A.S.	FR
Tobi 300mg/5ml,solution pour inhalation par nébuliseur	NL/H/4274/001	3400938071924	NOVARTIS PHARMA S.A.S.	FR
TOBI 300 mg/5 ml roztok pre rozprašovač	not available	15/0264/03-S	NOVARTIS, S.R.O.	SK
TOBI 300 mg/5 ml Nebuliser Solution	NL/H/4274/001	PA 13/123/1	NOVARTIS PHARMACEUTICALS UK LIMITED	IE
TOBI 300 mg/5 ml, lösning för nebulisator	NL/H/4274/001	16319	NOVARTIS SVERIGE AB	SE
TOBI® 300 mg/5 ml Nebuliser Solution	NL/H/4274/001	PL 00101/0935	NOVARTIS PHARMACEUTICALS UK LIMITED	UK
TOBI 300 mg/5 ml Nebuliser Solution	not available	15/312/03-C	NOVARTIS, S.R.O.	CZ
Tobi® διάλυμα για εισπνοή με εκνεφωτή 300mg/5ml	not available	19439	NOVARTIS PHARMACEUTICALS UK LIMITED	CY
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
Bramitob 300 mg/4 ml purškiamasis įkvepiamasis tirpalas	not available	LT/1/11/2643/001	CHIESI PHARMACEUTICALS GMBH	LT

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Bramitob 300 mg/4 ml purškiamasis įkvepiamasis tirpalas	not available	LT/1/11/2643/002	CHIESI PHARMACEUTICALS GMBH	LT
Bramitob 300 mg/4 ml purškiamasis įkvepiamasis tirpalas	not available	LT/1/11/2643/003	CHIESI PHARMACEUTICALS GMBH	LT
BRAMITOB 300 mg/4 ml šķīdums izsmidzināšanai	not available	11-0276	CHIESI PHARMACEUTICALS GMBH	LV
BRAMITOB 300 mg/4 ml otopina za atomizator	not available	UP/I-530-09/13-02/226	CHIESI PHARMACEUTICALS GMBH	HR
Bramitob 300 mg/4 ml purškiamasis įkvepiamasis tirpalas	not available	LT/1/11/2643/004	CHIESI PHARMACEUTICALS GMBH	LT
Tobramycin "SUN", inhalationsvæske til nebulisator, opløsning	NL/H/3560/001	56567	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	DK
Tobramycin SUN 300 mg Lösung für einen Vernebler	NL/H/3560/001	95878.00.00	SUN PHARMACEUTICALS GERMANY GMBH	DE
Tobramycyna SUN, 300 mg/5 mL, roztwór do nebulizacji	NL/H/3560/001	23837	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	PL
Tobramycine SUN 300 mg/5 ml verneveloplossing	NL/H/3560/001	RVG 117965	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NL
Tobramycin 300 mg/ 5 ml nebuliser solution	NL/H/3560/001	PL 31750/0087	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	UK
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

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Tobramicină SUN 300 mg soluție pentru nebulizator	NL/H/3560/001	9993/2017/02	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	RO
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
Tobramicina SUN 300 mg/5 ml soluzione per nebulizzatore	NL/H/3560/001	044611034	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	IT
Tobramicina SUN 300 mg/5 ml solución para inhalación por nebulizador	NL/H/3560/001	82287	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	ES
Tobramicina Accord 300 mg/5 ml solución para inhalación por nebulizador	PT/H/0504/001	75344	ACCORD HEALTHCARE S.L.U.	ES
Tobramicina Accord 300 mg/5 ml Solução para Inalação por Nebulização	PT/H/0504/001	5455860	ACCORD HEALTHCARE LIMITED	PT
Tobramycin Teva® 300 mg/5 ml Steri-Neb® Lösung für einen Vernebler	UK/H/4346/001	81406.00.00	TEVA GMBH	DE
Tobramicina Teva 300 mg / 5 ml Soluzione per nebulizzatore	UK/H/4346/001	041632011	TEVA ITALIA S.R.L.	IT
Tobramicina Teva 300 mg / 5 ml Soluzione per nebulizzatore	UK/H/4346/001	041632023	TEVA ITALIA S.R.L.	IT

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Tobramicina Teva 300 mg / 5 ml Soluzione per nebulizzatore	UK/H/4346/001	041632035	TEVA ITALIA S.R.L.	IT
Tobramycin 300 mg/5 ml Nebuliser Solution	UK/H/4346/001	PL 00289/1437	TEVA UK LIMITED	UK
Tobramycin "Teva", inhalationsvæske til nebulisator, opløsning	UK/H/4346/001	46486	TEVA DENMARK A/S	DK
Tobramicina Teva, 300 mg/5 ml, Solução para Inalação por Nebulização	UK/H/4346/001	5552716	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Tobramicina Teva 300 mg/5 ml solución para inhalación por nebulizador	UK/H/4346/001	75.612	TEVA PHARMA S.L.U	ES
Tymbrineb 300 mg/5 ml Nebuliser Solution	UK/H/4346/001	PA0749/117/001	TEVA PHARMA B.V.	IE
Tobramycine Steri-Neb 300 mg/5 ml, verneveloplossing	UK/H/4346/001	RVG 106999	TEVA NEDERLAND B.V.	NL
Tobramycin Via pharma 300 mg/5 ml purškiamasis įkvepiamasis tirpalas	LT/H/0112/001	LT/1/16/3931/001	UAB VIA PHARMA	LT
Tobramycin Via pharma 300 mg/5 ml šķīdums izsmidzināšanai	LT/H/0112/001	16-0100	UAB VIA PHARMA	LV
Tobramycin Via pharma 300 mg/5 ml nebuliseeritav lahus	LT/H/0112/001	911916	UAB VIA PHARMA	EE
Тобрамицин Виа фарма 300 mg/5 ml разтвор за небулизатор	LT/H/0112/001	20160288	UAB VIA PHARMA	BG

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Tobramycin Via pharma 300 mg/ 5 ml oldat porlasztásra	LT/H/0112/001	OGYI-T-23038/01	UAB VIA PHARMA	HU
Tobramycin Via pharma, 300 mg/5 ml, roztwór do nebulizacji	LT/H/0112/001	23633	UAB VIA PHARMA	PL
Tobramycin Via pharma 300 mg/5 ml soluție pentru inhalare prin nebulizator	LT/H/0112/001	9235/2016/01	UAB VIA PHARMA	RO
BRAMITOB, verneveloplossing 300 mg/4 ml	IT/H/0132/001	RVG 33841	CHIESI PHARMACEUTICALS B.V.	NL
BRAMITOB® 300 mg/4 ml Lösung für einen Vernebler	IT/H/0132/001	65777.00.00	CHIESI GMBH	DE
TOBRINEB 300 mg/4 ml soluzione da nebulizzare	IT/H/0132/001	036647028	PROMEDICA S.R.L.	IT
TOBRINEB 300 mg/4 ml soluzione da nebulizzare	IT/H/0132/001	036647042	PROMEDICA S.R.L.	IT
TOBRINEB 300 mg/4 ml soluzione da nebulizzare	IT/H/0132/001	036647016	PROMEDICA S.R.L.	IT
TOBRINEB 300 mg/4 ml soluzione da nebulizzare	IT/H/0132/001	036647030	PROMEDICA S.R.L.	IT
BRAMITOB 300 mg/4 ml Solución para inhalación por nebulizador	IT/H/0132/001	68621	CHIESI ESPAÑA, S.A.	ES
Bramitob 300mg/4ml Nebuliser Solution	IT/H/0132/001	PA 743/17/1	CHIESI LIMITED	IE
Bramitob 300mg/4ml Nebuliser Solution	IT/H/0132/001	PL 8829/0155	CHIESI LIMITED	UK



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Bramitob 300 mg/4 ml Lösung für einen Vernebler	IT/H/0132/001	1-26797	CHIESI PHARMACEUTICALS GMBH	AT
BRAMITOB	IT/H/0132/001	15/214/07-C	CHIESI PHARMACEUTICALS GMBH	CZ
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
Bramitob 300 mg/4 ml roztok na rozprašovanie	IT/H/0132/001	15/0534/06-S	CHIESI PHARMACEUTICALS GMBH	SK
BRAMITOB 300 mg/ 4 ml Διάλυμα για εισπνοή με εκνεφωτή σε περιέκτη μίας δόσης	IT/H/0132/001	77484/28-11-2007	CHIESI HELLAS A.E.B.E.	GR
Bramitob 300 mg/4 ml Solução para inalação por nebulização	IT/H/0132/001	5043955	CHIESI FARMACEUTICI S.P.A.	PT
Bramitob, 300 mg/4 ml, roztwór do nebulizacji	IT/H/0132/001	12796	CHIESI FARMACEUTICI S.P.A.	PL