10 September 2015
EMA/612853/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: tobramycin (nebuliser solution)

Procedure no.: PSUSA/00009316/201412

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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	IT/H/0132/001	1-26797	Chiesi Pharmaceuticals Gmbh	AT
Bramitob	IT/H/0132/001	15/214/07-C	Chiesi Pharmaceuticals Gmbh	CZ
Bramitob	IT/H/0132/001	65777.00.00	Chiesi Gmbh	DE
Bramitob	IT/H/0132/001	68621	Chiesi España, S.A.	ES
Bramitob	IT/H/0132/001	PL 08829/0155	Chiesi Limited	GB
Bramitob	IT/H/0132/001	77484/28-11-2007	Chiesi Hellas Aebe	GR
Bramitob		381-08-L/33382	Providens D.O.O.(Partner Chiesi)	HR
Bramitob	IT/H/0132/001	OGYI-T-20324/01	Chiesi Pharmaceuticals Gmbh	HU
Bramitob	IT/H/0132/001	OGYI-T-20324/02	Chiesi Pharmaceuticals Gmbh	HU
Bramitob	IT/H/0132/001	OGYI-T-20324/03	Chiesi Pharmaceuticals Gmbh	HU
Bramitob	IT/H/0132/001	OGYI-T-20324/04	Chiesi Pharmaceuticals Gmbh	HU
Bramitob	IT/H/0132/001	PA 743/17/1	Chiesi Limited	IE
Bramitob		LT/1/11/2643/001	Chiesi Pharmaceuticals Gmbh	LT
Bramitob		LT/1/11/2643/002	Chiesi Pharmaceuticals Gmbh	LT
Bramitob		LT/1/11/2643/003	Chiesi Pharmaceuticals Gmbh	LT

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Bramitob		11-0276	Chiesi Pharmaceuticals Gmbh	LV
Bramitob	IT/H/0132/001	RVG 33841	Chiesi Pharmaceuticals B.V.	NL
Bramitob	IT/H/0132/001	12796	Chiesi Pharmaceuticals Gmbh	PL
Bramitob	IT/H/0132/001	5043955	Angelini Farmaceutica Lda	PT
Bramitob	IT/H/0132/001	15/0534/06-S	Chiesi Pharmaceuticals Gmbh	SK
Tobi	UK/H/0361/001	1-23973	Novartis Pharma Gmbh (Art57)	AT
Tobi	UK/H/0361/001	BE219676	Novartis Pharma N.V. (Art57)	BE
Tobi		20050096	Novartis Pharma Gmbh (Art57)	BG
Tobi		19439	Novartis Pharmaceuticals Uk Limited (Art57)	CY
Tobi		15/312/03-C	Novartis, S.R.O. (Art57)	CZ
Tobi	UK/H/0361/001	49612.00.00	Novartis Pharma Gmbh (Art57)	DE
Tobi	UK/H/0361/001	31533	Novartis Healthcare A/S (Art57)	DK

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Tobi	UK/H/0361/001	63689	Novartis Farmacéutica S.A. (Art57)	ES
Tobi	UK/H/0361/001	15744	Novartis Finland Oy (Art57)	FI
Tobi	UK/H/0361/001	3400936572324	Novartis Pharma S.A.S. (Art57)	FR
Tobi	UK/H/0361/001	3400938071863	Novartis Pharma S.A.S. (Art57)	FR
Tobi	UK/H/0361/001	3400938071924	Novartis Pharma S.A.S. (Art57)	FR
Tobi	UK/H/0361/001	PL 00101/0935	Novartis Pharmaceuticals Uk Limited (Art57)	GB
Tobi	UK/H/0361/001	248950101	Novartis (Hellas) S.A.C.I. (Art57)	GR
Tobi	UK/H/0361/001	248950102	Novartis (Hellas) S.A.C.I. (Art57)	GR
Tobi	UK/H/0361/001	248950103	Novartis (Hellas) S.A.C.I. (Art57)	GR
Tobi		OGYI-T-8707/01	Novartis Hungária Kft. Pharma (Art57)	HU
Tobi		OGYI-T-8707/02	Novartis Hungária Kft. Pharma (Art57)	HU
Tobi		OGYI-T-8707/03	Novartis Hungária Kft. Pharma (Art57)	HU

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Tobi	UK/H/0361/001	PA 13/123/1	Novartis Pharmaceuticals Uk Limited (Art57)	IE
Tobi	UK/H/0361/001	034767018	Novartis Europharm Limited (Art57)	IT
Tobi	UK/H/0361/001	2000/11/00/32	Novartis Pharma N.V. (Art57)	LU
Tobi	UK/H/0361/001	RVG 25484	Novartis Pharma B.V. (Art57)	NL
Tobi	UK/H/0361/001	00-2577	Novartis Norge As (Art57)	NO
Tobi		R/10562	Novartis Pharma Gmbh (Art57)	PL
Tobi	UK/H/0361/001	3424389	Novartis Farma - Produtos Farmacêuticos S.A. Art57	PT
Tobi		5004/2004/01	Novartis Pharma Gmbh (Art57)	RO
Tobi		5004/2004/02	Novartis Pharma Gmbh (Art57)	RO
Tobi		5004/2004/03	Novartis Pharma Gmbh (Art57)	RO
Tobi	UK/H/0361/001	16319	Novartis Sverige Ab (Art57)	SE
Tobi		15/0264/03-S	Novartis, S.R.O. (Art57)	SK

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Tobramicina Combino	PT/H/504/01/DC	5455860	Combino Pharm Portugal, Unipessoal Lda	PT
Tobramicina Combino Pharm	PT/H/504/01/DC	75344	Combino Pharm S.L	ES
Tobramicina Teva	UK-H-4346-01-DC	75612	Teva Pharma S.L.U.; C/A Segura, 11, Edificio Albatros B, 1a Planta, Alcobendas, 28108, Madrid,spain	ES
Tobramicina Teva	UK-H-4346-01-DC	041632011	Teva Italia S.R.L.	IT
Tobramicina Teva	UK-H-4346-01-DC	041632023	Teva Italia S.R.L.	IT
Tobramicina Teva	UK-H-4346-01-DC	041632035	Teva Italia S.R.L.	IT
Tobramicina Teva	UK-H-4346-01-DC	5552716	Teva Pharma – Produtos Farmacêuticos Lda	PT
Tobramycin	UK-H-4346-01-DC	PL 00289/1437	Teva Uk Limited Brampton Road, Hampden Park	GB
Tobramycin Teva	UK-H-4346-01-DC	81406.00.00	Teva Gmbh	DE
Tobramycin Teva	UK-H-4346-01-DC	46486	Teva Denmark A/S	DK
Tobramycin Teva	UK-H-4346-01-DC	PA 749/117/1	Teva Pharma B.V. Computerweg 10	IE
Tobramycine 300 Mg/5 Ml Teva	UK-H-4346-01-DC	RVG 106999	Teva Nederland B.V.	NL

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Tobrineb	IT/H/0132/001	036647016	Promedica S.R.L.	IT
Tobrineb	IT/H/0132/001	036647028	Promedica S.R.L.	IT
Tobrineb	IT/H/0132/001	036647030	Promedica S.R.L.	IT
Tobrineb	IT/H/0132/001	036647042	Promedica S.R.L.	IT