



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 May 2021
EMA/353328/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: tobramycin (systemic use)

Procedure no.: PSUSA/00009318/202009



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 B. Braun 1 mg/ml soluzione per infusione.	DE/H/1096/001	040421024	B.BRAUN MELSUNGEN AG	IT
Tobramicina B. Braun 1 mg/ml soluzione per infusione.	DE/H/1096/001	040421012	B.BRAUN MELSUNGEN AG	IT
Tobramycin B. Braun 1 mg/ml Infusionslösung	DE/H/1096/001	1-29023	B.BRAUN MELSUNGEN AG	AT
Tobramycin B. Braun 1 mg/ml Infusionslösung	DE/H/1096/001	69217.00.00	B.BRAUN MELSUNGEN AG	DE
Tobramycin B. Braun 1 mg/ml Infusionslösung	DE/H/1096/001	2010040084	B.BRAUN MELSUNGEN AG	LU
Tobramycin B. Braun 1 mg/ml infusjonsvæske, oppløsning	DE/H/1096/001	07-4952	B.BRAUN MELSUNGEN AG	NO
Tobramycin B. Braun 1 mg/ml infuusioneste, liuos	DE/H/1096/001	23512	B.BRAUN MELSUNGEN AG	FI
Tobramycin B. Braun, 1 mg/ml, roztwór do infuzji	DE/H/1096/001	17626	B.BRAUN MELSUNGEN AG	PL
Tobramycin B. Braun 1 mg/ml infusionsvätska, lösning	DE/H/1096/001	23512	B.BRAUN MELSUNGEN AG	FI
NEBICINA® flaconcino 100 mg/2 ml	not available	023189018	TEOFARMA S.R.L.	IT
OBRACIN 40 mg/ml solution injectable	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	1637/97033919	EUROCEPT INTERNATIONAL BV	LU
Obracin 80 mg/ 2 ml, oplossing voor injectie 40 mg/ml	not available	RVG06890	EUROCEPT INTERNATIONAL BV	NL
OBRACIN 40 mg / ml oplossing voor injectie	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
OBRACIN 40 mg / ml	not available	1997033919	EUROCEPT INTERNATIONAL	LU

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Solution injectable			BV	
Nebcina, injeksjonsvæske, oppløsning	not available	06331	EUROCEPT INTERNATIONAL BV	DK
Nebcina 40 mg/ml injeksjonsvæske, oppløsning	not available	6161	EUROCEPT INTERNATIONAL BV	NO
TobraZid INFECTOPHARM 80 mg/2 ml Injektions-/Infusionslösung	not available	94949.00.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Tobramicina B. Braun 3 mg/ml soluzione per infusione.	DE/H/1096/002	040421048	B.BRAUN MELSUNGEN AG	IT
Tobramicina B. Braun 3 mg/ml soluzione per infusione.	DE/H/1096/002	040421051	B.BRAUN MELSUNGEN AG	IT
Tobramicina B. Braun 3 mg/ml soluzione per infusione.	DE/H/1096/002	040421063	B.BRAUN MELSUNGEN AG	IT
Tobramicina B. Braun 3 mg/ml soluzione per infusione.	DE/H/1096/002	040421036	B.BRAUN MELSUNGEN AG	IT
Tobramycin B. Braun 3 mg/ml Infusionslösung	DE/H/1096/002	1-29024	B.BRAUN MELSUNGEN AG	AT
Tobramycin B. Braun 3 mg/ml Infusionslösung	DE/H/1096/002	69218.00.00	B.BRAUN MELSUNGEN AG	DE
Tobramycin B. Braun 3 mg/ml Infusionslösung	DE/H/1096/002	2010040085	B.BRAUN MELSUNGEN AG	LU
Tobramycin B. Braun 3 mg/ml infusjonsvæske, oppløsning	DE/H/1096/002	07-4953	B.BRAUN MELSUNGEN AG	NO
Tobramycin B. Braun 3 mg/ml infuusioneste, liuos	DE/H/1096/002	23513	B.BRAUN MELSUNGEN AG	FI
Tobramycin B. Braun, 3 mg/ml, roztwór do infuzji	DE/H/1096/002	17627	B.BRAUN MELSUNGEN AG	PL
Tobramycin B. Braun 3 mg/ml infusionsvätska,	DE/H/1096/002	23513	B.BRAUN MELSUNGEN AG	FI

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lösning				
OBRACIN 40 mg/ml solution injectable	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	1637/97033919	EUROCEPT INTERNATIONAL BV	LU
Obracin 80 mg/ 2 ml, oplossing voor injectie 40 mg/ml	not available	RVG06890	EUROCEPT INTERNATIONAL BV	NL
OBRACIN 40 mg / ml oplossing voor injectie	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
OBRACIN 40 mg / ml Solution injectable	not available	1997033919	EUROCEPT INTERNATIONAL BV	LU
Nebcina, injektionsvæske, opløsning	not available	06331	EUROCEPT INTERNATIONAL BV	DK
Nebcina 40 mg/ml injeksjonsvæske, oppløsning	not available	6161	EUROCEPT INTERNATIONAL BV	NO
TobraZid INFECTOPHARM 40 mg/1 ml Injektions-/Infusionslösung	not available	94948.00.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
OBRACIN 40 mg/ml solution injectable	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	1637/97033919	EUROCEPT INTERNATIONAL BV	LU
Obracin 80 mg/ 2 ml, oplossing voor injectie 40 mg/ml	not available	RVG06890	EUROCEPT INTERNATIONAL BV	NL
OBRACIN 40 mg / ml oplossing voor injectie	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
OBRACIN 40 mg / ml Solution injectable	not available	1997033919	EUROCEPT INTERNATIONAL BV	LU
Nebcina, injektionsvæske,	not available	06331	EUROCEPT INTERNATIONAL	DK

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opløsning			BV	
Nebcina 40 mg/ml injeksjonsvæske, oppløsning	not available	6161	EUROCEPT INTERNATIONAL BV	NO
TOBRASIX® 160 mg / 2 ml Injektionslösung bzw. Konzentrat zur Herstellung einer Infusionslösung	not available	1-19875	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	AT
NEBCINE 25 mg, solution injectable	not available	34009 316 485 4 3	LABORATOIRE XO	FR
NEBCINE 25 mg, solution injectable	not available	34009 561 924 7 2	LABORATOIRE XO	FR
NEBCINE 100 mg, solution injectable	not available	34009 316 487 7 2	LABORATOIRE XO	FR
NEBCINE 75 mg, solution injectable	not available	34009 316 486 0 4	LABORATOIRE XO	FR
NEBCINE 75 mg, solution injectable	not available	34009 561 923 0 4	LABORATOIRE XO	FR
OBRACIN 40 mg/ml solution injectable	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
Obracin 40 mg/ml Injektionslösung	not available	1637/97033919	EUROCEPT INTERNATIONAL BV	LU
Obracin 80 mg/ 2 ml, oplossing voor injectie 40 mg/ml	not available	RVG06890	EUROCEPT INTERNATIONAL BV	NL
OBRACIN 40 mg / ml oplossing voor injectie	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
OBRACIN 40 mg / ml Solution injectable	not available	1997033919	EUROCEPT INTERNATIONAL BV	LU
Nebcina, injeksjonsvæske, oppløsning	not available	06331	EUROCEPT INTERNATIONAL BV	DK
Nebcina 40 mg/ml injeksjonsvæske, oppløsning	not available	6161	EUROCEPT INTERNATIONAL BV	NO

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Obracin 40 mg/ml Injektionslösung	not available	1637/97033919	EUROCEPT INTERNATIONAL BV	LU
Obracin 80 mg/ 2 ml, oplossing voor injectie 40 mg/ml	not available	RVG06890	EUROCEPT INTERNATIONAL BV	NL
OBRACIN 40 mg / ml oplossing voor injectie	not available	BE095304	EUROCEPT INTERNATIONAL BV	BE
OBRACIN 40 mg / ml Solution injectable	not available	1997033919	EUROCEPT INTERNATIONAL BV	LU
Nebcina, injektionsvæske, opløsning	not available	06331	EUROCEPT INTERNATIONAL BV	DK
Nebcina 40 mg/ml injeksjonsvæske, oppløsning	not available	6161	EUROCEPT INTERNATIONAL BV	NO
Nebcina 80 mg/ml injektionsvätska, lösning	not available	09862	MEDA AB	SE
Nebcina 10 mg/ml injektionsvätska, lösning	not available	09729	MEDA AB	SE
Nebcina 40 mg/ml injektionsvätska, lösning	not available	09271	MEDA AB	SE
Tobra-Gobens 100, 100 mg/2ml, solução injetável	not available	3861986	LABORATÓRIOS NORMON, S.A.	PT
Tobra-Gobens 100, 100 mg/2ml, solução injetável	not available	2206886	LABORATÓRIOS NORMON, S.A.	PT
Tobra-Gobens 50, 50 mg/2 ml, solução injetável	not available	2206787	LABORATÓRIOS NORMON, S.A.	PT
Tobra-Gobens 50, 50 mg/2 ml, solução injetável	not available	3861887	LABORATÓRIOS NORMON, S.A.	PT