



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/141741/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): amikacin

Procedure No.: PSUSA/00000143/201706



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
amic, 100 mg, solução injectável	not available	46083394	JABA RECORDATI, S.A.	PT
amic, 100 mg, solução injectável	not available	9624015	JABA RECORDATI, S.A.	PT
amic, 500 mg, solução injectável	not available	4608493	JABA RECORDATI, S.A.	PT
amic, 500 mg, solução injectável	not available	9624007	JABA RECORDATI, S.A.	PT
Amicacina B. Braun 10 mg/mL solução para perfusão	DE/H/1771/003	5355953	B.BRAUN MELSUNGEN AG	PT
Amicacina B. Braun 10 mg/mL solução para perfusão	DE/H/1771/003	5355946	B.BRAUN MELSUNGEN AG	PT
Amicacina B. Braun 2.5 mg/mL solução para perfusão	DE/H/1771/001	5355904	B.BRAUN MELSUNGEN AG	PT
Amicacina B. Braun 2.5 mg/mL solução para perfusão	DE/H/1771/001	5355912	B.BRAUN MELSUNGEN AG	PT
Amicacina B. Braun 5 mg/mL solução para perfusão	DE/H/1771/002	5355938	B.BRAUN MELSUNGEN AG	PT
Amicacina B. Braun 5 mg/mL solução para perfusão	DE/H/1771/002	5355920	B. BRAUN MELSUNGEN AG ART 57	PT
Amicacina Hikma	not available	2443893	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Amicacina Hikma	not available	2258994	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Amicacina Hikma	not available	4686499	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Amicacina Hikma	not available	2259091	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT

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Amicacina Hikma	not available	2443992	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Amicacina Hikma	not available	4686598	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Amicacina Hikma	not available	5462551	HIKMA FARMACÊUTICA (PORTUGAL), S.A.	PT
Amikacin B. Braun 10 mg/ml	DE/H/1771/003	23455/30-03-2012	B. BRAUN MELSUNGEN AG ART 57	GR
Amikacin B. Braun 10 mg/ml Infusionslösung	DE/H/1771/003	74068.00.00	B.BRAUN MELSUNGEN AG	DE
Amikacin B. Braun 10 mg/ml Infusionslösung	DE/H/1771/002	2012030003	B. BRAUN MELSUNGEN AG ART 57	LU
Amikacin B. Braun 10 mg/ml infusioónilahus	DE/H/1771/003	727511	B. BRAUN MELSUNGEN AG ART 57	EE
Amikacin B. Braun 10 mg/ml infuzní roztok	DE/H/1771/003	15/088/11-C	B. BRAUN MELSUNGEN AG ART 57	CZ
Amikacin B. Braun 10 mg/ml oldatos infúzió	DE/H/1771/003	OGYI-T-21811/04	B.BRAUN MELSUNGEN AG	HU
Amikacin B. Braun 10 mg/ml oldatos infúzió	DE/H/1771/003	OGYI-T-21811/03	B.BRAUN MELSUNGEN AG	HU
Amikacin B. Braun 10 mg/ml Infúzný roztok	DE/H/1771/003	15/0964/10-S	B.BRAUN MELSUNGEN AG	SK
Amikacin B. Braun 2,5 mg/ml	DE/H/1771/001	22848/30-03-2012	B. BRAUN MELSUNGEN AG ART 57	GR
Amikacin B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	1-30968	B. BRAUN MELSUNGEN AG ART 57	AT
Amikacin B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	74066.00.00	B.BRAUN MELSUNGEN AG	DE
Amikacin B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	2012030001	B. BRAUN MELSUNGEN AG ART 57	LU
Amikacin B. Braun 5 mg/ml	DE/H/1771/002	23454/30-03-2012	B. BRAUN MELSUNGEN AG ART 57	GR
Amikacin B. Braun 5	DE/H/1771/002	1-30969	B. BRAUN MELSUNGEN AG	AT

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mg/ml Infusionslösung			ART 57	
Amikacin B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	74067.00.00	B.BRAUN MELSUNGEN AG	DE
Amikacin B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	2012030002	B. BRAUN MELSUNGEN AG ART 57	LU
Amikacin B. Braun 5 mg/ml infusioonilahus	DE/H/1771/002	727611	B. BRAUN MELSUNGEN AG ART 57	EE
Amikacin B. Braun 5 mg/ml infuzní roztok	DE/H/1771/002	15/087/11-C	B. BRAUN MELSUNGEN AG ART 57	CZ
Amikacin B. Braun 5 mg/ml Infúzný roztok	DE/H/1771/002	15/0963/10-S	B.BRAUN MELSUNGEN AG	SK
Amikacin B. Braun 5 mg/ml oldatos infúzió	DE/H/1771/002	OGYI-T-21811/02	B.BRAUN MELSUNGEN AG	HU
Amikacin B. Braun 5 mg/ml oldatos infúzió	DE/H/1771/002	OGYI-T-21811/01	B.BRAUN MELSUNGEN AG	HU
Amikacin B. Braun, 10 mg/ml, roztwór do infuzji	DE/H/1771/003	18757	B. BRAUN MELSUNGEN AG ART 57	PL
Amikacin B. Braun, 2,5 mg/ml, roztwór do infuzji	DE/H/1771/001	18755	B. BRAUN MELSUNGEN AG ART 57	PL
Amikacin B. Braun, 5 mg/ml, roztwór do infuzji	DE/H/1771/002	18756	B. BRAUN MELSUNGEN AG ART 57	PL
Amikacin B. Braun 10 mg/ml šķīdums infūzijām	DE/H/1771/003	11-0078	B. BRAUN MELSUNGEN AG ART 57	LV
Amikacin B. Braun 5 mg/ml šķīdums infūzijām	DE/H/1771/002	11-0079	B. BRAUN MELSUNGEN AG ART 57	LV
Amikacina B. Braun 10 mg/ml, soluzione per infusione	DE/H/1771/003	041000050/M	B.BRAUN MELSUNGEN AG	IT
Amikacina B. Braun 10 mg/ml, soluzione per infusione	DE/H/1771/003	041000062/M	B.BRAUN MELSUNGEN AG	IT
Amikacina B. Braun 5 mg/ml, soluzione per	DE/H/1771/002	041000035/M	B.BRAUN MELSUNGEN AG	IT

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infusione				
Amikacina B. Braun 5 mg/ml, soluzione per infusione	DE/H/1771/002	041000047/M	B.BRAUN MELSUNGEN AG	IT
AMIKACINE B BRAUN 10 mg/ml, solution pour perfusion	DE/H/1771/003	34009 579 535 2 2	B.BRAUN MELSUNGEN AG	FR
AMIKACINE B BRAUN 10 mg/ml, solution pour perfusion	DE/H/1771/003	34009 579 536 9 0	B.BRAUN MELSUNGEN AG	FR
Amikacine B. Braun 10 mg/ml oplossing voor infusie	DE/H/1771/003	BE393373	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 10 mg/ml solution pour perfusion	DE/H/1771/003	BE393373	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 2,5 mg/ml oplossing voor infusie	DE/H/1771/001	BE393355	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 2,5 mg/ml solution pour perfusion	DE/H/1771/001	BE393355	B.BRAUN MELSUNGEN AG	BE
AMIKACINE B. BRAUN 2,5 mg/ml, solution pour perfusion	DE/H/1771/001	34009 579 231 3 6	B.BRAUN MELSUNGEN AG	FR
AMIKACINE B. BRAUN 2,5 mg/ml, solution pour perfusion	DE/H/1771/001	34009 579 233 6 5:	B.BRAUN MELSUNGEN AG	FR
Amikacine B. Braun 5 mg/ml oplossing voor infusie	DE/H/1771/002	BE393364	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 5 mg/ml solution pour	DE/H/1771/002	BE393364	B.BRAUN MELSUNGEN AG	BE

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perfusion				
AMIKACINE B. BRAUN 5 mg/ml, solution pour perfusion	DE/H/1771/002	34009 579 529 2 1	B.BRAUN MELSUNGEN AG	FR
AMIKACINE B. BRAUN 5 mg/ml, solution pour perfusion	DE/H/1771/002	34009 579 530 0 3:	B.BRAUN MELSUNGEN AG	FR
Amikacine Mylan 1 g, poudre pour solution injectable en flacon	not available	NL 25 688	MYLAN S.A.S	FR
Amikacine Mylan 250 mg, poudre pour solution injectable	not available	NL 19 708	MYLAN S.A.S	FR
Amikacine Mylan 50 mg/1 ml, enfants et nourrissons, solution injectable	not available	NL 19 707	MYLAN S.A.S	FR
Amikacine Mylan 500 mg, poudre pour solution injectable	not available	NL 19709	MYLAN S.A.S	FR
AMIKIN INJECTION 100MG/2ML	not available	PA 0048/004/004	BRISTOL-MYERS SQUIBB HOLDINGS LIMITED	IE
AMIKIN INJECTION 100MG/2ML	not available	PL 00125/0090R	BRISTOL-MYERS SQUIBB HOLDINGS LIMITED	UK
AMUKIN 1 g / 4 ml solution injectable	not available	BE173652	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
AMUKIN 1 g / 4 ml solution injectable	not available	2010080835-0224731	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
AMUKIN 100 mg / 2 ml solution injectable	not available	BE107125	BRISTOL-MYERS SQUIBB BELGIUM S.A.	BE
AMUKIN 100 mg / 2 ml solution injectable	not available	2010080833-0005573	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
AMUKIN 500 mg / 2 ml	not available	BE107116	BRISTOL-MYERS SQUIBB	BE

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solution injectable			BELGIUM S.A.	
AMUKIN 500 mg / 2 ml solution injectable	not available	2010080834-0005590	BRISTOL-MYERS SQUIBB BELGIUM S.A.	LU
BIKLIN 250 mg - Stechampullen	not available	16.299	BRISTOL-MYERS SQUIBB GESMBH	AT
Biklin 250 mg/ml injektionsvätska, lösning	not available	9437	BRISTOL-MYERS SQUIBB AB	SE
BIKLIN 500 mg - Stechampullen	not available	16.300	BRISTOL-MYERS SQUIBB GESMBH	AT
Biklin® 250 mg/ml injektionsvätska	not available	10883	BRISTOL-MYERS SQUIBB AB	FI
BRIKLIN® 1000 mg/4ml VIAL	not available	27652	VIANEX S.A.	GR
BRIKLIN® 250 mg/2ml VIAL	not available	46024	VIANEX S.A.	GR
BRIKLIN® 500 mg/2ml VIAL	not available	17009	VIANEX S.A.	GR
LIKACIN 5% Gel	not available	024475081	LAB. IT. BIOCHIM. FARM.CO LISAPharma S.P.A.	IT
NEKACIN "1000 mg soluzione iniettabile"	not available	033190036	NEW RESEARCH SRL	IT
NEKACIN "500 mg soluzione iniettabile"	not available	033190024	NEW RESEARCH SRL	IT
Амикацин Б. Браун 10 mg/ml инфузионен разтвор	DE/H/1771/003	20110132	B.BRAUN MELSUNGEN AG	BG
Амикацин Б. Браун 2,5 mg/ml инфузионен разтвор	DE/H/1771/001	20110130	B.BRAUN MELSUNGEN AG	BG
Амикацин Б. Браун 5 mg/ml инфузионен разтвор	DE/H/1771/002	20110131	B.BRAUN MELSUNGEN AG	BG

