



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 January 2023
EMA/3792/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): amikacin (except for centrally authorised products)

Procedure No. PSUSA/00000143/202206



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
Amikacin B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	1-30968	B.BRAUN MELSUNGEN AG	AT
Amikacin B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	1-30969	B.BRAUN MELSUNGEN AG	AT
AMUKIN 500 mg / 2 ml solution injectable	not available	BE107116	LABORATOIRES DELBERT	BE
AMUKIN 1 g / 4 ml solution injectable	not available	BE173652	LABORATOIRES DELBERT	BE
AMUKIN 500 mg / 2 ml oplossing voor injectie	not available	BE107116	LABORATOIRES DELBERT	BE
AMUKIN 1 g / 4 ml oplossing voor injectie	not available	BE173652	LABORATOIRES DELBERT	BE
AMUKIN 1 g / 4 ml Injektionslösung	not available	BE173652	LABORATOIRES DELBERT	BE
AMUKIN 500 mg / 2 ml Injektionslösung	not available	BE107116	LABORATOIRES DELBERT	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 Infusionslösung	DE/H/1771/001	BE393355	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	BE393355	B.BRAUN MELSUNGEN AG	BE
Amikacine Fresenius Kabi 5 mg/ml oplossing voor infusie	DE/H/5638/001	BE556266	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5 mg/ml oplossing voor infusie	DE/H/5638/001	BE 556284	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5 mg/ml oplossing voor infusie	DE/H/5638/001	BE 556275	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5 mg/ml solution pour perfusion.	DE/H/5638/001	BE556266	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5 mg/ml solution pour perfusion	DE/H/5638/001	BE 556284	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5 mg/ml solution pour perfusion	DE/H/5638/001	BE 556275	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5	DE/H/5638/001	BE556266	FRESENIUS KABI NV/SA	BE

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mg/ml Infusionslösung				
Amikacine Fresenius Kabi 5 mg/ml Infusionslösung	DE/H/5638/001	BE 556284	FRESENIUS KABI NV/SA	BE
Amikacine Fresenius Kabi 5 mg/ml Infusionslösung	DE/H/5638/001	BE 556275	FRESENIUS KABI NV/SA	BE
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 perfusion	DE/H/1771/002	BE393364	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	BE393364	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	BE393364	B.BRAUN MELSUNGEN AG	BE
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 10 mg/ml Infusionslösung	DE/H/1771/003	BE393373	B.BRAUN MELSUNGEN AG	BE
Amikacine B. Braun 10 mg/ml Infusionslösung	DE/H/1771/003	BE393373	B.BRAUN MELSUNGEN AG	BE
AMUKIN 500 mg / 2 ml solution injectable	not available	BE107116	LABORATOIRES DELBERT	BE
AMUKIN 1 g / 4 ml solution injectable	not available	BE173652	LABORATOIRES DELBERT	BE
AMUKIN 500 mg / 2 ml oplossing voor injectie	not available	BE107116	LABORATOIRES DELBERT	BE
AMUKIN 1 g / 4 ml oplossing voor injectie	not available	BE173652	LABORATOIRES DELBERT	BE
AMUKIN 1 g / 4 ml Injektionslösung	not available	BE173652	LABORATOIRES DELBERT	BE
AMUKIN 500 mg / 2 ml Injektionslösung	not available	BE107116	LABORATOIRES DELBERT	BE
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
Амикацин Б. Браун 10 mg/ml инфузионен разтвор	DE/H/1771/003	20110132	B.BRAUN MELSUNGEN AG	BG
Amikacin/Kabi 5 mg/ml	DE/H/5638/001	023285	FRESENIUS KABI HELLAS A.E.	CY

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διάλυμα για έγχυση				
Amikacin Fresenius Kabi 5 mg/ml infuzní roztok	DE/H/5638/001	15/200/18-C	FRESENIUS KABI S.R.O.	CZ
Amikacin B. Braun 5 mg/ml infuzní roztok	DE/H/1771/002	15/087/11-C	B.BRAUN MELSUNGEN AG	CZ
Amikacin B. Braun 10 mg/ml infuzní roztok	DE/H/1771/003	15/088/11-C	B.BRAUN MELSUNGEN AG	CZ
Amikacin B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	74066.00.00	B.BRAUN MELSUNGEN AG	DE
Amikacin Kabi 5 mg/ml Infusionslösung	DE/H/5638/001	2202301.00.00	FRESENIUS KABI DEUTSCHLAND GMBH	DE
Amikacin B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	74067.00.00	B.BRAUN MELSUNGEN AG	DE
Amikacin B. Braun 10 mg/ml Infusionslösung	DE/H/1771/003	74068.00.00	B.BRAUN MELSUNGEN AG	DE
Amikacin B. Braun 5 mg/ml infusioonilahus	DE/H/1771/002	727611	B.BRAUN MELSUNGEN AG	EE
Amikacin B. Braun 10 mg/ml infusioonilahus	DE/H/1771/003	727511	B.BRAUN MELSUNGEN AG	EE
Amikacina Kabi 5 mg/ml solución para perfusión	DE/H/5638/001	85.160	FRESENIUS KABI ESPAÑA S.A.U.	ES
Amikacin Fresenius Kabi 5 mg/ml infuusioneste, liuos	DE/H/5638/001	36119	FRESENIUS KABI AB	FI
AMIKACINE VIATRIS 50 mg/1 ml, solution injectable	not available	NL19707	VIATRIS SANTE	FR
AMIKACINE VIATRIS 50 mg/1 ml, solution injectable	not available	NL19707	VIATRIS SANTE	FR
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 VIATRIS 250 mg, poudre pour solution injectable	not available	NL19708	VIATRIS SANTE	FR
AMIKACINE VIATRIS 500 mg, poudre pour solution injectable	not available	NL19709	VIATRIS SANTE	FR
AMIKACINE VIATRIS 1 g, poudre pour solution injectable en flacon	not available	NL25688	VIATRIS SANTE	FR
AMIKACINE KABI 5 mg/mL, solution pour perfusion	DE/H/5638/001	34009 550 720 7 2	FRESENIUS KABI FRANCE S.A.S.	FR

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AMIKACINE KABI 5 mg/mL, solution pour perfusion	DE/H/5638/001	34009 550 720 5 8	FRESENIUS KABI FRANCE S.A.S.	FR
AMIKACINE KABI 5 mg/mL, solution pour perfusion	DE/H/5638/001	34009 550 720 8 9	FRESENIUS KABI FRANCE S.A.S.	FR
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 B. BRAUN 10 mg/ml, solution pour perfusion	DE/H/1771/003	34009 300 557 6 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 VIATRIS 250 mg, poudre pour solution injectable	not available	NL19708	VIATRIS SANTE	FR
AMIKACINE VIATRIS 500 mg, poudre pour solution injectable	not available	NL19709	VIATRIS SANTE	FR
AMIKACINE VIATRIS 1 g, poudre pour solution injectable en flacon	not available	NL25688	VIATRIS SANTE	FR
Amikacin B. Braun 2,5 mg/ml	DE/H/1771/001	22848/30-03-2012	B.BRAUN MELSUNGEN AG	GR
Amikacin/Kabi 5 mg/ml διάλυμα για έγχυση	DE/H/5638/001	61318/12-06-2020	FRESENIUS KABI HELLAS A.E.	GR
BRIKLIN® 250 mg/2ml VIAL	not available	74856/19/20-01-2020	VIANEX S.A.	GR
BRIKLIN® 500 mg/2ml VIAL	not available	2081/20-01-2020	VIANEX S.A.	GR
BRIKLIN® 1000 mg/4ml VIAL	not available	27652/20-04-2011	VIANEX S.A.	GR
Amikacin B. Braun 5 mg/ml	DE/H/1771/002	23454/30-03-2012	B.BRAUN MELSUNGEN AG	GR
Amikacin B. Braun 10 mg/ml	DE/H/1771/003	23455/30-03-2012	B.BRAUN MELSUNGEN AG	GR
Amikacin Kabi 5 mg/ml oldatos infúzió	DE/H/5638/001	OGYI-T-23646/01	FRESENIUS KABI HUNGARY KFT.	HU
Amikacin Kabi 5 mg/ml oldatos infúzió	DE/H/5638/001	OGYI-T-23646/02	FRESENIUS KABI HUNGARY KFT.	HU
Amikacin Kabi 5 mg/ml oldatos infúzió	DE/H/5638/001	OGYI-T-23646/03	FRESENIUS KABI HUNGARY KFT.	HU
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 5 mg/ml Solution for infusion	DE/H/5638/001	PA 2059/072/001	FRESENIUS KABI DEUTSCHLAND GMBH	IE
NEKACIN "500 mg soluzione	not available	033190024	NEW RESEARCH SRL	IT

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iniettabile"				
NEKACIN "1000 mg soluzione iniettabile"	not available	033190036	NEW RESEARCH SRL	IT
DRAMIGEL 5% gel	not available	028947012	MORGAN SRL	IT
LIKACIN 5% Gel	not available	024475081	LAB. IT. BIOCHIM. FARM.CO LISAPHARMA S.P.A.	IT
Amikacina B. Braun 5 mg/ml, soluzione per infusione	DE/H/1771/002	041000035/M	B.BRAUN MELSUNGEN AG	IT
Amikacina B. Braun 5 mg/ml, soluzione per infusione	DE/H/1771/002	041000047/M	B.BRAUN MELSUNGEN AG	IT
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
AMUKIN 500 mg / 2 ml solution injectable	not available	2010080834	LABORATOIRES DELBERT	LU
AMUKIN 1 g / 4 ml solution injectable	not available	2010080835	LABORATOIRES DELBERT	LU
AMUKIN 1 g / 4 ml Injektionslösung	not available	2010080835	LABORATOIRES DELBERT	LU
AMUKIN 500 mg / 2 ml Injektionslösung	not available	2010080834	LABORATOIRES DELBERT	LU
Amikacin B. Braun 2,5 mg/ml Infusionslösung	DE/H/1771/001	2012030001	B.BRAUN MELSUNGEN AG	LU
Amikacin B. Braun 5 mg/ml Infusionslösung	DE/H/1771/002	2012030002	B.BRAUN MELSUNGEN AG	LU
Amikacin B. Braun 10 mg/ml Infusionslösung	DE/H/1771/003	2012030003	B.BRAUN MELSUNGEN AG	LU
AMUKIN 500 mg / 2 ml solution injectable	not available	2010080834	LABORATOIRES DELBERT	LU
AMUKIN 1 g / 4 ml solution injectable	not available	2010080835	LABORATOIRES DELBERT	LU
AMUKIN 1 g / 4 ml Injektionslösung	not available	2010080835	LABORATOIRES DELBERT	LU
AMUKIN 500 mg / 2 ml Injektionslösung	not available	2010080834	LABORATOIRES DELBERT	LU
Amikacin B. Braun 5 mg/ml šķīdums infūzijām	DE/H/1771/002	11-0079	B.BRAUN MELSUNGEN AG	LV
Amikacin B. Braun 10 mg/ml šķīdums infūzijām	DE/H/1771/003	11-0078	B.BRAUN MELSUNGEN AG	LV

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Amikacin B. Braun, 2,5 mg/ml, roztwór do infuzji	DE/H/1771/001	18755	B.BRAUN MELSUNGEN AG	PL
Amikacin Kabi, 5 mg/ml, roztwor do infuzji	DE/H/5638/001	25995	FRESENIUS KABI POLSKA SP. Z O.O.	PL
Amikacin B. Braun, 5 mg/ml, roztwór do infuzji	DE/H/1771/002	18756	B.BRAUN MELSUNGEN AG	PL
Amikacin B. Braun, 10 mg/ml, roztwór do infuzji	DE/H/1771/003	18757	B.BRAUN MELSUNGEN AG	PL
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
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
Amicacina Kabi 5 mg/ml solução para perfusão	DE/H/5638/001	5807037	FRESENIUS KABI PHARMA PORTUGAL, LDA.	PT
Amicacina Kabi 5 mg/ml solução para perfusão	DE/H/5638/001	5807045	FRESENIUS KABI PHARMA PORTUGAL, LDA.	PT
Amicacina Kabi 5 mg/ml solução para perfusão	DE/H/5638/001	5807052	FRESENIUS KABI PHARMA PORTUGAL, LDA.	PT
Amikacin Fresenius Kabi 5 mg/ml infusionsvätska. lösning	DE/H/5638/001	57895	FRESENIUS KABI AB	SE
Biklin 250 mg/ml injektionsvätska, lösning	not available	9437	VIANEX S.A.	SE
Amikacin Kabi 5 mg/ml raztopina za infundiranje	DE/H/5638/001	H/20/02740/001	FRESENIUS KABI DEUTSCHLAND GMBH	SI
Amikacin Kabi 5 mg/ml raztopina za infundiranje	DE/H/5638/001	H/20/02740/003	FRESENIUS KABI DEUTSCHLAND GMBH	SI
Amikacin Kabi 5 mg/ml raztopina za infundiranje	DE/H/5638/001	H/20/02740/002	FRESENIUS KABI DEUTSCHLAND GMBH	SI
Amikacin Fresenius Kabi 5 mg/ml, infúzny roztok	DE/H/5638/001	15/0066/20-S	FRESENIUS KABI S.R.O.	SK

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Amikacin B. Braun 5 mg/ml Infúzny roztok	DE/H/1771/002	15/0963/10-S	B.BRAUN MELSUNGEN AG	SK
Amikacin B. Braun 10 mg/ml Infúzny roztok	DE/H/1771/003	15/0964/10-S	B.BRAUN MELSUNGEN AG	SK
AMIKIN INJECTION 100MG/2ML	not available	PL 08616/0004	VIANEX S.A.	UK (NI)
Amikacin Kabi 5 mg/ml solution for infusion	DE/H/5638/001	PL 08828/0283	FRESENIUS KABI LIMITED	UK (NI)