



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2021
EMA/85487/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: benzylpenicillin

Procedure no.: PSUSA/00000383/202006



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
Penicilline 1.000.000 IE, poeder voor oplossing voor injectie	not available	BE101516	KELA PHARMA NV	BE
Penicilline 1.000.000 UI, poudre pour solution injectable	not available	BE101516	KELA PHARMA NV	BE
Penicilline 1.000.000 UI, poudre pour solution injectable	not available	0170/09080444	KELA PHARMA NV	LU
Penicilline 2.000.000. IE, poeder voor oplossing voor injectie	not available	BE101491	KELA PHARMA NV	BE
Penicilline 2.000.000 UI, poudre pour solution injectable	not available	BE101491	KELA PHARMA NV	BE
Penicilline 2.000.000 UI, poudre pour solution injectable	not available	0170/09080445	KELA PHARMA NV	LU
Penicilline 5.000.000 IE, poeder voor oplossing voor injectie	not available	BE101473	KELA PHARMA NV	BE
Penicilline 5.000.000 UI, poudre pour solution injectable	not available	BE101473	KELA PHARMA NV	BE
Penicilline 5.000.000 UI, poudre pour solution injectable	not available	0170/09080446	KELA PHARMA NV	LU

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
Penicilline 1.000.000 IE, Pulver zur Herstellung einer Injektionslösung.	not available	BE101516	KELA PHARMA NV	BE
Penicilline 2.000.000 IE, Pulver zur Herstellung einer Injektionslösung.	not available	BE101491	KELA PHARMA NV	BE
Penicilline 5.000.000 IE, Pulver zur Herstellung einer Injektionslösung.	not available	BE101473	KELA PHARMA NV	BE
Penicilina Atral 20 M.U.I Pó para solução injectável	not available	4651998	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 20 M.U.I Pó para solução injectável	not available	4652095	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	4651790	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	4651899	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	5922596	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 20 M.U.I. Pó para solução injectável	not available	4651592	LABORATÓRIOS ATRAL, S.A.	PT

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Penicilina Atral 20 M.U.I. Pó para solução injectável	not available	4651691	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	4651394	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	4651493	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	5922695	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	9818302	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 20 M.U.I. Pó para solução injectável	not available	9818310	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 1 M.U.I. Pó para solução injectável	not available	9818328	LABORATÓRIOS ATRAL, S.A.	PT
Penicilina Atral 20 M.U.I. Pó para solução injectável	not available	9818336	LABORATÓRIOS ATRAL, S.A.	PT
Geepenil 606 mg pulver till injektionsvätska, lösning	not available	9925	ORION OYJ	FI

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
Geepenil 6,06 g pulver till infusionsvätska, lösning	not available	9926	ORION OYJ	FI
Geepenil 6,06 g infuusiokuiva-aine, liuosta varten	not available	9926	ORION OYJ	FI
Geepenil 606 mg injektiokuiva-aine, liuosta varten	not available	9925	ORION OYJ	FI
Penicillin Actavis 600 mg (1 millj. a.e.) stungulyfs-/innrennslisstofn, lausn	not available	IS/1/03/143/01	ACTAVIS GROUP PTC EHF.	IS
Penicillin Actavis 1,2 g (2 millj. a.e.) stungulyfs-/innrennslisstofn, lausn	not available	IS/1/03/143/02	ACTAVIS GROUP PTC EHF.	IS
Penicillin Actavis 3 g (5 millj. a.e.) stungulyfs-/innrennslisstofn, lausn	not available	IS/1/03/143/03	ACTAVIS GROUP PTC EHF.	IS
Penicillin G INFECTOPHARM® 5 Mega 5 Millionen I.E., Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	42702.01.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Penicilină G potasică Atb 1000000 UI pulbere pentru soluție injectabilă	not available	9129/2016/01	ANTIBIOTICE SA	RO

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
Penicilină G potasică Atb 1000000 UI pulbere pentru soluție injectabilă	not available	9129/2016/02	ANTIBIOTICE SA	RO
Penicilină G potasică Atb 1000000 UI pulbere pentru soluție injectabilă	not available	9129/2016/03	ANTIBIOTICE SA	RO
Penicilină G potasică Atb 1000000 UI pulbere pentru soluție injectabilă	not available	9129/2016/04	ANTIBIOTICE SA	RO
Penicilină G sodică Atb1000000 UI pulbere pentru soluție injectabilă	not available	9153/2016/01	ANTIBIOTICE SA	RO
Penicilină G sodică Atb1000000 UI pulbere pentru soluție injectabilă	not available	9153/2016/02	ANTIBIOTICE SA	RO
Penicilină G sodică Atb1000000 UI pulbere pentru soluție injectabilă	not available	9153/2016/03	ANTIBIOTICE SA	RO
Penicilină G sodică Atb 1000000 UI pulbere pentru soluție injectabilă	not available	9153/2016/04	ANTIBIOTICE SA	RO
Penicilină G sodică Atb 400000 UI pulbere pentru soluție injectabilă	not available	10904/2018/01	ANTIBIOTICE SA	RO
Penicilină G sodică Atb 400000 UI pulbere pentru soluție injectabilă	not available	10904/2018/02	ANTIBIOTICE SA	RO

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
Penicilină G sodică Atb 400000 UI pulbere pentru soluție injectabilă	not available	10904/2018/03	ANTIBIOTICE SA	RO
Penicilină G sodică Atb 400000 UI pulbere pentru soluție injectabilă	not available	10904/2018/04	ANTIBIOTICE SA	RO
Penicillin Actavis 600 mg (1 mill. IE) pulver til injeksjonsvæske/infusions væske, oppløsning	not available	2497	ACTAVIS GROUP PTC EHF.	NO
Penicillin Actavis 6 g (10 mill. IE) pulver til injeksjonsvæske/infusions væske, oppløsning	not available	07-4771	ACTAVIS GROUP PTC EHF.	NO
Penicillin Actavis 1,2 g (2 mill. IE) pulver til injeksjonsvæske/infusions væske, oppløsning	not available	07-4769	ACTAVIS GROUP PTC EHF.	NO
Penicillin Actavis 3 g (5 mill. IE) pulver til injeksjonsvæske/infusions væske, oppløsning	not available	07-4770	ACTAVIS GROUP PTC EHF.	NO
Benzylpenicillin sodium 600mg Powder for Injection	not available	PL 06831/0213	GENUS PHARMACEUTICALS LIMITED	UK
Benzylpenicillin sodium 1200mg Powder for Injection	not available	PL 06831/0284	GENUS PHARMACEUTICALS LIMITED	UK

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
Penicillin G INFECTOPHARM® 10 Mega 10 Millionen I.E., Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	3000333.02.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Natriumbenzylpenicilline Sandoz 1.000.000 IE, poeder voor oplossing voor injectie of infusie	AT/H/0659/002	RVG 120400	SANDOZ B.V.	NL
Natriumbenzylpenicilline Sandoz 10.000.000 IE, poeder voor oplossing voor injectie of infusie	AT/H/0659/004	RVG 120402	SANDOZ B.V.	NL
Natriumbenzylpenicilline Sandoz 500.000 IE, poeder voor oplossing voor injectie of infusie	AT/H/0659/001	RVG 120396	SANDOZ B.V.	NL
Natriumbenzylpenicilline Sandoz 5.000.000 IE, poeder voor oplossing voor injectie of infusie	AT/H/0659/003	RVG 120401	SANDOZ B.V.	NL
Penicillin G-Natrium Sandoz 500.000 IE – Trochsensteehampulle	AT/H/0659/001	12784	SANDOZ GMBH	AT
Penicillin G-Natrium Sandoz 1 Mega IE – Trochsensteehampulle	AT/H/0659/002	12785	SANDOZ GMBH	AT

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
Penicillin G-Natrium Sandoz 5 Mega IE – Trockenstechampulle	AT/H/0659/003	12786	SANDOZ GMBH	AT
Penicillin G-Natrium Sandoz 10 Mega IE – Trockenstechampulle	AT/H/0659/004	12787	SANDOZ GMBH	AT
Bensylpenicillin Meda 3 g pulver till injektions/infusionsvätska, lösning	not available	3521	MEDA AB	SE
Bensylpenicillin Meda 1 g pulver till injektions/infusionsvätska, lösning	not available	3521	MEDA AB	SE
Penicillinum Crystallisatum TZF, 1 000 000 j.m., proszek do sporządzania roztworu do wstrzykiwań	not available	R/3109	TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA	PL
Penicillinum Crystallisatum TZF, 3 000 000 j.m., proszek do sporządzania roztworu do wstrzykiwań	not available	R/3110	TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA	PL
Penicillinum Crystallisatum TZF, 5 000 000 j.m., proszek do sporządzania roztworu do wstrzykiwań	not available	R/3613	TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA	PL

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
PENICILLINE G PANPHARMA 5 000 000 UI, poudre pour usage parentéral	not available	34009 277 223 8 7	PANPHARMA	FR
Benzylpenicillin "Panpharma"	NO/H/0101/001	32499	PANPHARMA	DK
Benzylpenicillin "Panpharma"	NO/H/0101/001	32507	PANPHARMA	DK
Benzylpenicillin "Panpharma"	NO/H/0101/001	32508	PANPHARMA	DK
Benzylpenicillin "Panpharma"	NO/H/0101/001	32509	PANPHARMA	DK
Benzylpenicillin Panpharma 0,6 g, injektio-/infuusiokuiva- aine, liuosta varten	NO/H/0101/001	16563	PANPHARMA	FI
Benzylpenicillin Panpharma 1,2 g, injektio-/infuusiokuiva- aine, liuosta varten	NO/H/0101/002	16594	PANPHARMA	FI
Benzylpenicillin Panpharma 3 g, injektio- /infuusiokuiva-aine, liuosta varten	NO/H/0101/003	16595	PANPHARMA	FI

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
Benzylpenicillin Panpharma pulver till injektions- /infusionsvätska, lösning 0,6 g	NO/H/0101/001	17332	PANPHARMA	SE
Benzylpenicillin Panpharma pulver till injektions- /infusionsvätska, lösning 1,2 g	NO/H/0101/002	17332	PANPHARMA	SE
Benzylpenicillin Panpharma pulver till injektions- /infusionsvätska, lösning 3 g	NO/H/0101/003	17332	PANPHARMA	SE
Benzylpenicillin Panpharma pulver till injektions- /infusionsvätska, lösning 6 g	NO/H/0101/004	17332	PANPHARMA	SE
Benzylpenicillin Panpharma pulver til injeksjonsvæske/infusions væske, oppløsning 0,6 g	NO/H/0101/001	97-5066	PANPHARMA	NO
Benzylpenicillin Panpharma pulver til injeksjonsvæske/infusions væske, oppløsning 1,2 g	NO/H/0101/002	06-4134	PANPHARMA	NO

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
Benzylpenicillin Panpharma pulver til injeksjonsvæske/infusjons væske, oppløsning 3 g	NO/H/0101/003	06-4135	PANPHARMA	NO
Benzylpenicillin Panpharma pulver til injeksjonsvæske/infusjons væske, oppløsning 6 g	NO/H/0101/004	06-4136	PANPHARMA	NO
PAN – PENICILLIN G 1 000 000 SV pulveris injeksiju šķīduma pagatavošanai	not available	99-0239	PANPHARMA	LV
PAN – PENICILLIN G 1 000 000 SV pulveris injeksiju šķīduma pagatavošanai	not available	99-0239	PANPHARMA	LV
PAN – PENICILLIN G 1 000 000 SV pulveris injeksiju šķīduma pagatavošanai	not available	99-0239	PANPHARMA	LV
PAN – PENICILLIN G 1 000 000 SV pulveris injeksiju šķīduma pagatavošanai	not available	99-0239	PANPHARMA	LV
PAN – PENICILLIN G 5 000 000 SV pulveris injeksiju šķīduma pagatavošanai	not available	99-0240	PANPHARMA	LV

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
PAN – PENICILLIN G 5 000 000 SV pulveris injekciju šķīduma pagatavošanai	not available	99-0240	PANPHARMA	LV
PAN – PENICILLIN G 5 000 000 SV pulveris injekciju šķīduma pagatavošanai	not available	99-0240	PANPHARMA	LV
PAN – PENICILLIN G 5 000 000 SV pulveris injekciju šķīduma pagatavošanai	not available	99-0240	PANPHARMA	LV
PAN-PENICILLIN G SODIUM 1 mln. TV miltelīti injekciniam ar infuzinam tirpalui	not available	LT/1/98/0662/001	PANPHARMA	LT
PAN-PENICILLIN G SODIUM 5 mln. TV miltelīti injekciniam ar infuzinam tirpalui	not available	LT/1/98/0662/002	PANPHARMA	LT
Pan Peni G 1 MIU prašak za otopinu za injekciju/infuziju	not available	HR-H-314045399	PANPHARMA	HR
Pan Peni G 10 MIU prašak za otopinu za injekciju/infuziju	not available	HR-H-936454442	PANPHARMA	HR
PENICILLINE G PANPHARMA 1 000 000 UI, poudre pour usage	not available	34009 365 820 8 8	PANPHARMA	FR

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
parentéral				
PENICILLINE G PANPHARMA 1 000 000 UI, poudre pour usage parentéral	not available	34009 559 764 6 2	PANPHARMA	FR
PENICILLINE G PANPHARMA 1 000 000 UI, poudre pour usage parentéral	not available	34009 559 765 2 3	PANPHARMA	FR
PENICILLINE G PANPHARMA 5 000 000 UI, poudre pour usage parentéral	not available	34009 365 646 8 8	PANPHARMA	FR
PENICILLINE G PANPHARMA 5 000 000 UI, poudre pour usage parentéral	not available	34009 559 767 5 2	PANPHARMA	FR
PENICILLINE G PANPHARMA 5 000 000 UI, poudre pour usage parentéral	not available	34009 559 768 1 3	PANPHARMA	FR
PENICILLINE G PANPHARMA 5 000 000 UI, poudre pour usage parentéral	not available	34009 559 769 8 1	PANPHARMA	FR

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
PENICILLINE G PANPHARMA 1 000 000 UI, poudre pour usage parentéral	not available	34009 300 728 5 1	PANPHARMA	FR
PAN-PENICILLIN G SODIUM 1 mln. TV milteliai injekciniam ar infuzinam tirpalui	not available	LT/1/98/0662/003	PANPHARMA	LT
PAN-PENICILLIN G SODIUM 5 mln. TV milteliai injekciniam ar infuzinam tirpalui	not available	LT/1/98/0662/004	PANPHARMA	LT
Crystapen 600mg Powder for Solution for Injection or Infusion	not available	PA0126/313/001	CLONMEL HEALTHCARE LTD.	IE
Penicillin G Sodium Sandoz 1 000 000 TV milteliai injekciniam ar infuziniam tirpalui	not available	LT/1/95/1468/001	SANDOZ GMBH	LT
BENZILPENICILLINA POTASSICA K24 PHARMACEUTICALS 1'000'000 UI/4ml polvere e solvente per soluzione iniettabile	not available	036981013	K24 PHARMACEUTICALS	IT
BENZILPENICILLINA POTASSICA K24 PHARMACEUTICALS 1'000'000 UI polvere per	not available	036981025	K24 PHARMACEUTICALS	IT

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soluzione iniettabile				
SODIOPEN 2.000.000 U.I.	not available	46.169	LABORATORIO REIG JOFRE, S.A.	ES
Penicillin G INFECTOPHARM® 1 Mega 1 Million I.E., Pulver zur Herstellung einer Injektions- bzw. Infusionslösung	not available	3000333.03.00	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	DE
Penicillin G Sodium Sandoz 1 000 000 SV pulveris injekciju vai infūziju šķīduma pagatavošanai	not available	99-0550	SANDOZ GMBH	LV
Penicillin G-Natrium Sandoz 10 Mega IE - Trockensubstanz zur Infusionsbereitung	not available	15886	SANDOZ GMBH	AT
PENILEVEL 1.000.000 U.I.	not available	33.580	LABORATORIOS ERN, S.A.	ES
Benzylpenicillinenatrium Sandoz 10.000.000 I.E., poeder voor injectievloeistof	not available	RVG 57667	SANDOZ B.V.	NL

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Benzylpenicillinenatrium Sandoz 1.000.000 I.E., poeder voor injectievloeistof	not available	RVG 53418	SANDOZ B.V.	NL
Penicillin G Sodium Sandoz, 1 000 000 RÜ süste- või infusioonilahuse pulber	not available	244599	SANDOZ GMBH	EE
Benzylpenicillin sodium 600mg Powder for Injection	not available	PL 06831/0213	GENUS PHARMACEUTICALS LIMITED	UK
Benzylpenicillin sodium 1200mg Powder for Injection	not available	PL 06831/0284	GENUS PHARMACEUTICALS LIMITED	UK
Penicillin 1 000 000 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-2893/01	TEVA GYÓGYSZERGYÁR ZRT	HU
Penicillin 1 000 000 NE por és oldószer oldatos injekcióhoz	not available	OGYI-T-2893/02	TEVA GYÓGYSZERGYÁR ZRT	HU
PENIBIOT "1" INJECTABLE	not available	44812	LABORATORIOS NORMON, S.A.	ES
PENIBIOT "5" Inyectable	not available	43893	LABORATORIOS NORMON, S.A.	ES
PENIBIOT "2" Inyectable	not available	46.145	LABORATORIOS NORMON, S.A.	ES

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
SODIOPEN 5.000.000 U.I.	not available	46.168	LABORATORIO REIG JOFRE, S.A.	ES
BENZYL PENICILLIN / COOPER	not available	AA1001/00701	COOPER S.A. PHARMACEUTICALS	MT
BENZYL PENICILLIN / COOPER	not available	24459/07-12-2017	COOPER S.A. PHARMACEUTICALS	GR