



РЕПУБЛИКА БЪЛГАРИЯ

Министерство на здравеопазването

Министър на здравеопазването

ЗАПОВЕД

24.6.2025 г.

X РД-01-291/24.06.2025 г.

Signed by: IVO TSVETANOV MANCHEV

На основание чл. 25, ал. 4 от Закона за администрацията, чл. 266а, ал. 2 от Закона за лекарствените продукти в хуманната медицина, чл. 16, ал. 4 от Наредба № 10 от 2011 г. за условията и реда за лечение с неразрешени за употреба в Република България лекарствени продукти, лекарствени продукти, прилагани извън условията на разрешението за употреба и лекарствени продукти за състрадателна употреба, както и за условията и реда за включване, промени, изключване и доставка на лекарствени продукти от списъка по чл. 266а, ал. 2 от Закона за лекарствените продукти в хуманната медицина

НАРЕЖДАМ:

I. Утвърждавам списък на лекарствените продукти по чл. 266а, ал. 2 от Закона за лекарствените продукти в хуманната медицина, съгласно Приложението.

II. Отменям Заповед № РД-01-387/24.06.2024 г., изменена и допълнена със Заповед № РД-01-532/15.07.2024 г., Заповед № РД-01-539/22.07.2024 г., Заповед № РД-01-601/16.08.2024 г., Заповед № РД-01-605/20.08.2024 г., Заповед № РД-01-620/30.08.2024 г., Заповед № РД-01-643/17.09.2024 г., Заповед № РД-01-653/24.09.2024 г., Заповед № РД-01-689/09.10.2024 г., Заповед № РД-01-725/25.10.2024 г., Заповед РД-01-766/18.11.2024 г., Заповед РД-01-787/28.11.2024 г., Заповед № РД-01-829/03.12.2024 г., Заповед № РД-01-884/19.12.2024 г., Заповед № РД-01-915/30.12.2024 г., Заповед № РД-01-1/02.01.2025 г., Заповед № РД-01-12/10.01.2025 г., Заповед № РД-01-46/03.02.2025 г., Заповед № РД-01-49/07.02.2025 г., Заповед № РД-01-86/25.02.2025 г., Заповед № РД-01-99/05.03.2025 г., Заповед № РД-01-102/06.03.2025 г., Заповед № РД-01-116/14.03.2025 г., Заповед № РД-01-141/04.04.2025 г., Заповед № РД-01-171/28.04.2025 г., Заповед № РД-01-200/16.05.2025 г. и Заповед № РД-01-208/19.05.2025 г.

III. Настоящата заповед да се публикува на интернет страницата на Министерството на здравеопазването.

X Силви Кирилов

Доц. д-р Силви Кирилов, дм
Министър на здравеопазването
Signed by: Silvi Kirilov Petrov

Приложение

СПИСЪК

на лекарствените продукти по чл. 266а, ал. 2 от Закона за лекарствените продукти в хуманната медицина

№	Код по анатомо-терапевтично-химичната класификация	Международно непатентно наименование, към което принадлежи продуктът	Лекарствена форма и количество активно вещество	Заболяване по международен код на заболяванията	Допълнителна информация
1	L04AA24	Abatacept	250 mg powder for concentrate for solution for infusion	M05.0; M05.1; M05.3; M05.8;M08.30	
2	C01EA01	Alprostadil	20 micrograms powder for solution for infusion	Q25.1, Q25.5, Q20.3	
3	N07XX05	Amifampridine	10 mg tablets	G73.1	
4	L04AC03	Anakinra	100 mg/0.67 ml solution for injection in pre-filled syringe	U07.1;M08.2, M35.8; M05.0; M05.1; M05.3; M05.8;	
5	L01XX27	Arsenic trioxide	1 mg/ml concentrate for solution for infusion - 10 ml; 2 mg/ml concentrate for solution for infusion - 6 ml	C92.4	
6	P01BF05	Arteminol and Piperaquine	320 mg/40 mg film-coated tablets	B50.0; B50.8; B50.9	
7	P01BE03	Artesunate	110 mg powder and solvent for solution for injection	B50.0; B50.8; B50.9; B51.8 ; B53.1	

8	L01XX02	Asparaginase	10 000 U powder for concentrate for solution for infusion; 10 mg/0.5 ml solution for injection/infusion	Съгласно РУ	
9	J01DF01	Aztreonam	75 mg powder and solvent for nebuliser solution	E84.0	
10	J01DF51	Aztreonam and beta-lactamase inhibitor	1,5 g/0,5 g powder for concentrate for solution for infusion	Съгласно РУ	
11	A16AA06	Betaine	1 g oral powder	E72.1	
12	D03AX13	Betulae cortex	9.4 g gel 23.4 g gel	Q81.1, Q81.2	
13	M05BX05	Burosumab	10 mg solution for injection - 1 ml; 20 mg solution for injection - 1 ml; 30 mg solution for injection - 1 ml	E83.3	
14	L01AB01	Busulfan	6 mg/ml concentrate for solution for infusion - 10 ml	C90, C81, C82, C83, C85, C91, C92, D46, D47;D61.0, D61, D61.0, D61.1, D61.2, D61.3	
15	B06AC01	C1- inhibitor, plasma derived	3000 IU powder and solvent for solution for injection 2000 IU powder and solvent for solution for injection	D84.1	
16	L01EX07	Cabozantinib	60 mg film- coated tablets	C64, C22.0, C73	

17	N06BC01	Caffeine	20 mg/ml solution for infusion and oral solution - 3 ml; 20 mg/ml solution for infusion and oral solution - 1 ml; 10 mg/ml solution for infusion - 1ml	P28.3; P28.4, P22.9	
18	L04AC08	Canakinumab	150 mg powder for solution for injection	Съгласно РУ	
19	N03AX24	Cannabidiol	100 mg/ml oral solution 100 ml	G40.4; G40.8, G40.6, Q85.1	
20	B01AX07	Caplacizumab	10 mg powder and solvent for solution for injection	M31.1	
21	A16AA05	Carglumic acid	200 mg dispersible tablets	E71.0, E71.1, E72.2	
22	L01AD01	Carmustine	100 mg powder and solvent for concentrate for solution for infusion	C71.0, C71.1, C71.2, C71.3, C71.4, C71.5, C71.6, C71.7, C71.8, C71.9, C43.0, C43.1, C43.2, C43.3, C43.4, C43.5, C43.6, C43.7, C43.8, C43.9, C79.3, C79.4, C15-C20	
23	J06BD07	Casirivimab/Imdevimab	300 mg + 300 mg solution for injection/infusion - 2,5 ml (120 mg/ml)+2,5 ml (120 mg/ml)	U07.1	
24	J02AX04	Caspofungin	50 mg powder for concentrate for solution for infusion; 70 mg powder for concentrate for solution for infusion	Съгласно РУ	

25	J01DI04	Cefiderocol	1 g powder for concentrate for solution for infusion	G00.8	
26	S01XA24	Cenegermin	20 micrograms/ml eye drops, solution – 1 ml	H16.0, H16.1, H16.2	Само за лечение на невротрофичен кератит. Да бъде използван, когато са изчерпани другите възможности за терапевтично и хирургично повлияване.
27	A05AA01	Chenodeoxycholic acid	250 mg hard capsules	E75.5	
28	B02BD07	Coagulation factor XIII	250 IU powder and solvent for solution for injection/infusion	D68.2	
29	L01AA01	Cyclophosphamide	50 mg coated tablets	Съгласно РУ	
30	M03CA01	Dantrolene	120 mg powder for solution for injection	T88.3	
31	L01BC08	Decitabine	50 mg powder for concentrate for solution for infusion	C92.0	
32	B01AX01	Defibrotide	80 mg/ml concentrate for solution for infusion - 2,5 ml	C90, C81, C82, C83, C85, C91, C92, D46, D47, D61; Z94.8	
33	N01AB07	Desflurane	100% inhalation vapour, liquid - 240 ml	Съгласно РУ	
34	L01FX06	Dinutuximab beta	4,5 mg/ml concentrate for solution for infusion - 4,5 ml	от C76.0 до C76.8	
35	L01DB01	Doxorubicin	2 mg/ml concentrate for solution for infusion- 10 ml; 2 mg/ml concentrate for	C90, C81, C82, C83, C85, C91; C56, C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9,	

			solution for infusion- 25 ml	C46.0, C46.1, C46.2, C46.3, C46.7, C46.8, C46.9	
36	A16AB26	Eladocagene exuparvovec	2.8 x 10 ¹¹ vg/0.5 ml solution for infusion - 0.5 ml	E70.8	
37	B05XA31	Electrolytes in combination with other drugs	concentrate for solution for infusion 10 ml	K90.8, K90.9, K91.2, K91.8, P78.3	
38	L01FX08	Elotuzumab	300 mg powder for concentrate for solution for infusion ; 400 mg powder for concentrate for solution for infusion	C90.0	
39	J05AF10	Entecavir	0.05 mg/ml oral solution - 210 ml	B18; K 74.6	
40	B05BA02	Fat emulsions	emulsion for infusion -100 ml	E40 - E46, E50 - E64	
41	N03AX26	Fenfluramine	2.2 mg/ml oral solution -60 ml; 120 ml; 250 ml; 360 ml	G40.4, G40.6, G40.8	
42	N01AH01	Fentanyl	50 micrograms/ml solution for injection - 2 ml	Съгласно РУ	
43	A07AA12	Fidaxomicin	200 mg film-coated tablets	A04.7	
44	N03AX27	Ganaxolone	50 mg/mL oral suspension - 110 ml	G40.6, G40.4	
45	J05AB06	Ganciclovir	500 mg powder for concentrate for solution for infusion	B25, P35.1	

46	L01BC05	Gemcitabine	100 mg/ml concentrate for solution for infusion -10 ml	Съгласно РУ	
47	V03AF09	Glucarpidase	1 000 units powder for solution for injection	Съгласно РУ	
48	A16AX09	Glycerol phenylbutyrate	1.1 g/ml oral liquid - 25 ml	E71.0, E71.1, E72.2	
49	C02AC02	Guanfacine	1 mg prolonged- release tablets; 2 mg prolonged- release tablets; 3 mg prolonged- release tablets; 4 mg prolonged- release tablets	F90.0; F90.1;	
50	H02AB09	Hydrocortisone	5 mg modified- release hard capsules; 10 mg modified -release hard capsules	E25.0, E25.8, E27.1, E27.2	
51	H02AB09	Hydrocortisone	100 mg powder for solution for injection/infusio n	E23.0; E25.0; E25.8; E27.1; E27.2, E27.3, E27.4, E31.0, E89.3	
52	H02AB09	Hydrocortisone	5 mg modified- release tablet 20 mg Modified- release tablet	E25.0, E25.8, E27.1, E27.2, E27.3, E27.4, E31	
53	N06BX13	Idebenone	150 mg film- coated tablets	H47.2	
54	J06BA02;	Immunoglobulins, normal human, for intravascular adm.	100 mg/ml solution for infusion - 10 ml, 25 ml, 100 ml, 200 ml,300 ml, 400 ml; 50 mg/ml solution for infusion - 10 ml,20 ml, 50 ml, 100 ml, 200 ml, 400 ml, 500 ml	Съгласно РУ	

55	J06BA01	Immunoglobulins, normal human, for extravascular adm.	200 mg/ml solution for injection - 5 ml; 100 mg/ml Solution for infusion- 25 ml, 50 ml, 100 ml, 200 ml, 300 ml	Съгласно РУ	
56	B06AC05	Lanadelumab	150 mg solution for injection in pre-filled syringe 1 ml	D84.1	
57	L01EX12	Larotrectinib	20 mg/ml oral solution 100 ml	Съгласно РУ	
58	L04AX04	Lenalidomide	2.5 mg capsules, hard; 7,5 mg capsules, hard	C90.0	
59	J05AX18	Letermovir	480 mg concentrate for solution for infusion 24 ml	Съгласно РУ	
60	N03AX14	Levetiracetam	100 mg/ml concentrate for solution for infusion 5 ml	G40.6, G41.0, G41.1, G41.2, G41.8, G41.9	
61	N05BA06	Lorazepam	4 mg/ml solution for injection - 1 ml	G40.6, G41.0, G41.1, G41.2, G41.8, G41.9; T42.4	
62	V10X	Lutetium (177Lu) chloride	40 GBq/mL radiopharmaceutical precursor, solution - 2 ml; 3 ml; 10 ml	C 61; C00-C97	
63	B05BC01	Mannitol	15% solution for infusion - 500 ml	Съгласно РУ	

64	A05AX04	Maralixibat chloride	9.5 mg/ml oral solution 30 ml	Q44.7	
65	L01AA03	Melphalan	200 mg powder and solvent for concentrate for solution for infusion; 50 mg powder and solvent for concentrate for solution for infusion	C90, C81, C82, C83, C85, C91, C92, D46, D47, D61; C56, C50, Z94.9	
66	L01BB02	Mercaptopurine	20 mg/ml oral suspension -100 ml	C91.0	
67	J01DH52	Meropenem and vaborbactam	1 g/1 g powder for concentrate for solution for infusion	N 10, N11.0, N11.8, N11.9, N13.6, N15.1 N16.0; N39.0; J10-J18; J20-J22;	
68	V03AB17	Methylthioninium chloride	5 mg/ml solution for injection-10 ml 5 mg/ml solution for injection-2 ml	T65.5	
69	A16AA07	Metreleptin	3 mg powder for solution for injection; 5.8 mg powder for solution for injection; 11.3 mg powder for solution for injection	E88.1	
70	N05CD08	Midazolam	1 mg/ml solution for injection/infusion - 10 ml	T42.4	
71	L03AX15	Mifamurtide	4 mg powder for concentrate for dispersion for infusion	C40.0-C40.9, C41.0-C41.9,	

72	L01DC03	Mitomycin	20 mg powder for solution for injection/infusion or intravesical use ; 10 mg powder for solution for injection/infusion or intravesical use	C16.0, C16.1, C16.2, C16.3, C16.4, C16.5, C16.6, C16.8, C16.9, C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9, C34.0, C34.1, C34.2, C34.3, C34.8, C34.9, C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9 , C67.0, C67.1, C67.2, C67.3, C67.4, C67.5, C67.6, C67.7, C67.8, C67.9, C21	
73	L04AA06	Mycophenolic acid	500 mg powder for concentrate for solution for infusion	Z94.0, T86.1, Z94.4, T86.4	
74	L04AA06	Mycophenolic acid	1 g/5 ml powder for oral suspension	Z94.0, T86.1, Z94.4, T86.4, Z94.1, T86.2	
75	V03AB15	Naloxone	0.4 mg/ml solution for injection/infusion - 1 ml	T40.0, T40.1, T40.2, T40.3, T40.4.; Y50.1	
76	A16AX04	Nitisinone	4 mg/ml oral suspension - 90 ml	E70.2	
77	J01XE01	Nitrofurantoin	100 mg hard capsule	N10, N15.8, Q62.0, Q62.2, Q62.7; N11.0, N11.1, N11.8, N11.9	
78	C01CA03	Norepinephrine	1 mg/ml concentrate for solution for infusion 1 ml; 5 ml; 10 ml	Съгласно РУ	
79	A05AX05	Odevixibat	200 micrograms hard capsules; 400 micrograms hard capsules; 600 micrograms hard capsules; 1 200 micrograms hard capsules	K83.8; Q44.7	

80	N05AH03	Olanzapine	10 mg powder for solution for injection	F20	
81	A16AB25	Olipudase alfa	4 mg powder for concentrate for solution for infusion; 20 mg powder for concentrate for solution for infusion	E75.2	
82	N07XX25	Omaveloxolone	50 mg hard capsules	G11.1	
83	M09AX09	Onasemnogene abeparvovec	2×10 ¹³ vector genomes/ml solution for infusion 5.5 ml + 8.3 ml 2×10 ¹³ vector genomes/ml solution for infusion 8.3 ml	G12.0, G12.1	
84	N07XX11	Pitolisant	4.5 mg film-coated tablets; 18 mg film-coated tablets	G47.4	
85	L04AX06	Pomalidomide	1 mg hard capsules; 2 mg hard capsules; 3 mg hard capsules	C90.0	
86	J02AC04	Posaconazole	300 mg concentrate for solution for infusion 16,7 ml; 100 mg gastro-resistant tablets; 40 mg/ml oral suspension 105 ml	Съгласно PY	
87	A12BA30	Potassium (different salts in combination)	8 mEq prolonged-release granules; 24 mEq prolonged-release granules	N 25.0, N 25.1, N 25.8, N 25.9,N15.8	
88	J05AJ01	Raltegravir	100 mg granules for oral suspension; 25 mg chewable tablets; 100 mg chewable tablets	B20-B24	

89	V03AF07	Rasburicase	1.5 mg/ml powder and solvent for concentrate for solution for infusion	Съгласно РУ	
90	L04AJ02	Ravulizumab	300 mg/3 ml concentrate for solution for infusion 300 mg/30 ml concentrate for solution for infusion	D59.3, D59.5	
91	J06BD06	Regdanvimab	60 mg/ml concentrate for solution for infusion 16 ml	U07.1	
92	N05AX08	Risperidone	75 mg powder and solvent for prolonged-release suspension for injection	F20	
93	B01AF01	Rivaroxaban	1 mg/ml granules for oral suspension 2,625 g; 5,25 g	I82.8; I26; I48;Z 95.2;	
94	M03AC09	Rocuronium bromide	10 mg/ml solution for injection/infusion 10 ml	Съгласно РУ	
95	N03AF03	Rufinamide	100 mg film-coated tablets; 200 mg film-coated tablets; 400 mg film-coated tablets	G40,6, G40.4	
96	A16AB14	Sebelipase alfa	2 mg/ml concentrate for solution for infusion 10 ml	E75.5	
97	L04AC10	Secukinumab	Cosentyx 75 mg solution for injection in pre-filled syringe 0,5 ml	L40.0; M08.30,M08.41, M08.42 ,M08.43, M08.44, M08.45 ,M08.46, M08.47, M08.48, M08.18	
98	L01EE04;	Selumetinib	10 mg hard capsules; 25 mg hard capsules	Q85.0	
99	L04AC11;	Siltuximab	100 mg powder for concentrate for solution for infusion; 400 mg powder for concentrate	D47	

			for solution for infusion		
10 0	N07XX04	Sodium oxybate	500 mg/ml oral solution 180 ml	G47.4;	
10 1	H01CB01	Somatostatin	3 mg powder for solution for injection or infusion	K 25.0, K 26.0, K 28.0, K 29.0, K 91.8, K 91.9	
10 2	N03AX17	Stiripentol	250 mg hard capsules; 250 mg powder for oral suspension in sachet	G40.6, G40.4;G40.8	
10 3	V03AB35	Sugammadex	100 mg/ml solution for injection - 5 ml	Съгласно РУ	
10 4	L04AD02	Tacrolimus	5 mg/ml concentrate for solution for infusion - 1ml	Z94.0, T86.1, Z94.4, T86.4, Z94.1, T86.2;	
10 5	A16AX08	Teduglutide	1.25 mg powder and solvent for solution for injection	K90.9 , K91.2,K91.8	
10 6	L04AX02	Thalidomide	50 mg hard capsules; 100 mg coated tablets	C90.0	
10 7	L01AC01	Thiotepa	15 mg powder for concentrate for solution for infusion; 100 mg powder for concentrate for solution for infusion	Съгласно РУ	
10 8	L01FF13	Toripalimab	240 mg concentrate for solution for infusion	C11	

10 9	L01AB02	Treosulfan	5 g powder for solution for infusion	C90, C81, C82, C83, C85, C91, C92, D46, D47, D61	
11 0	L02AE04	Triptorelin	11,25 mg powder and solvent for prolonged- release suspension for injection	E22.8	
11 1	S01FA06	Tropicamide	5 mg/ml eye drops solution-10 ml	H00 - H59	
11 2	H02AB18	Vamorolone	40 mg/ml oral suspension	G71.0	
11 3	N03AG04	Vigabatrin	500 mg soluble tablets	G40.4, G40.6	
11 4	V07AB	Water for injections	solvent for parenteral use – 500 ml; solvent for parenteral use - 10 ml	Съгласно РУ	
11 5	A16AX05	Zinc acetate	50 mg hard capsules	E83	