



РЕПУБЛИКА БЪЛГАРИЯ

Министерство на здравеопазването

Министър на здравеопазването

ЗАПОВЕД

24.6.2024 г.

X РД-01-387/24.06.2024 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-01-356/22.06.2023 г. за утвърждаване на списък на лекарствените продукти по чл. 266а, ал. 2 от Закона за лекарствените продукти в хуманната медицина, допълнена със Заповед № РД-01-377/10.07.2023 г., Заповед № РД-01-403/21.07.2023 г. Заповед № РД-01- 412/27.07.2023 г., Заповед № РД-01-470/22.08.2023 г., Заповед № РД-01-536/03.10.2023 г., Заповед № РД-01-623/14.11.2023 г., Заповед № РД-01-623/14.11.2023 г., Заповед № РД-01-704/21.12.2023 г., Заповед РД-01-708/22.12.2023 г., Заповед РД-01-16/16.01.2024 г., Заповед РД-01-25/19.01.2024 г., Заповед РД-01-64/09.02.2024 г. и Заповед № РД-01-364/30.05.2024 г.

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

24.6.2024 г.

X Kondeva

Д-р Галя Кондева

Министър на здравеопазването

Signed by: Galya Georgieva Kondeva-Mankova

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	C01EA01	Alprostadil	20 mcg powder for solution for infusion x 10	I70.2, I73.0, I73.1, I74.2, I74.3, I74.5	
2	L01XD04	Aminolevulinic acid	30 mg/ml powder for oral solution - 50 ml	C71.0	
3	L04AC03	Anakinra	Solution for injection 100 mg/0,67 ml in pre-filled syringe	U07.1, M08.2, M35.8, M05.8, M06.1, M08.2, M10.0, M11.8, D84.9, M35.2	
4	L01XX27	Arsenic trioxide	1 mg/ml concentrate for solution for infusion - 10 ml	C92.4	
5	P01BF05	Arteminol and Piperaquine	320 mg/40 mg film-coated tablets x 3; x 6; x 9; x 12; x 270; x 300	B50	
6	P01BE03	Artesunate	110 mg - Powder and solvent for solution for injection- 2 vials + 2 vials; 4 vials + 4 vials	B50	
7	L01XX02	Asparaginase/ L-asparaginase	10 000 U powder for concentrate for solution for infusion x 1; x 5	C91.0	
8	M09AX03	Ataluren	1000 mg granules for oral suspension x 30 sachets	G71.0	

9	J01DF01	Aztreonam	75 mg powder and solvent for nebuliser solution - 84 vials + 88 ampoules; 84 vials + 88 ampoules + 1 altera nebuliser handset	E84.0	
10	H01CB01	Betaine anhydrous	1 g oral powder	E71.2	
11	D03AX13	Betulae cortex (Birch bark extract)	Gel Cutaneous 9,4 g ; 23,4 g	Q81.1, Q81.2	
12	M05BX05	Burosumab	solution for injection 10 mg/ml; solution for injection 20 mg/ml; solution for injection 30 mg/ml;	E83.3	
13	L01AB01	Busulfan	6 mg/ml concentrate for solution for infusion -10 ml x 8 (8 x 1) vials	C90, C81, C82, C83, C85, C91, C92, D46, D47;D61.0, D61, D61.0, D61.1, D61.2, D61.3	
14	B06AC01	C1- inhibitor, plasma derived	Powder and solvent for solution for injection 3000 IU - vial x 1; x 5; x 20; Powder and solvent for solution for injection 2000 IU- vial x 1; x 5; x 20	D84.1	
15	L01EX07	Cabozantinib	film-coated tablets 60 mg x 30 film-coated tablets 20 mg x 30	C64, C22.0, C73	
16	L04AC08	Canakinumab	150 mg powder for solution for injection vial	M06.1, M10.0, D84.9	
17	N03AX24	Cannabidiol	100 mg/ml oral solution (1 x 100 ml bottle+2 syringes of 1 ml + 2 syringes of 5ml+2 bottle adaptors и 3 x100 ml bottles+2 syringes of 1 ml+2 syringes of 5 ml+3 bottle adaptors.)	G40.4; G40.6	
18	B01AX07	Caplacizumab	10 mg/10 ml powder and solvent for solution for injection	M31.1, D69.3	
19	A16AA05	Carglumic acid	dispersible tablets 200 mg x 5; 15; 12; 60	E71.0, E71.1, E72.2	
20	L01AD01	Carmustin	Powder and solvent for concentrtrate for solution for infusion 100 mg	C81, C82, C83, C84, C85, C71, C15-C26, C43	

21	J06BD07	Casirivimab/Imdevimab	300 mg + 300 mg solution for injection/infusion - 2,5 ml (300mg of casirivimab per 2,5 ml and 300 mg of imdevimab per 2,5 ml);120mg/ml + 120mg/ml solution for injection/infusion -11,1 ml (1332mg of casirivimab per 11,1 ml and 1332 mg of imdevimab per 11,1 ml)	U07.1	
22	J02AX04	Caspofungin	50 mg powder for concentrate for solution for infusion x 1 vial; 70 mg powder for concentrate for solution for infusion x 1 vial	Съгласно РУ	
23	J01DI04	Cefiderocol	1 g powder for concentrate for solution for infusion	B96.5, B96.1, B96.2, U83.7	
24	B02BD07	Coagulation factor XIII	250 IU powder and solvent for solution for injection/infusion x 1 vial; 1250 IU powder and solvent for solution for injection/infusion x 1 vial	D68.2	
25	L01AA01	Cyclophosphamide	50 mg coated tablets x 50; 200; 500; 1000	G70.2;C82.0,C82.1,C82.2,C82.7, C82.9, C84.4, C84.5, C85.1,C85.7,C85.9, C88.0, C88.9, C90.0, C90.1, C90.2, C92.0, C92.1, C92.3, C92.7, C95.0,C95.1,C95.2,C95.7, C91.1, D59.1, D69.3, D69.0, M30.2, M31.3, M32.1, M32.8, M33.0, M33.2; C91.0, C81, C85, C90, C56, C62, C50, C34, C74, C41, C49, C41, C92; N01.0 до N01.8; N00.0 до N00; N03.0 до N03.8; N04.0 до N04.8; N05.0 до N05.9; M32.1*; N08.5; M30.0*; M31.0*; M31.1*; M31.3*; N16.4; N08.2; E85;*N08.4	

26	L01BC08	Decitabine	50 mg powder for concentrate for solution for infusion x 1 vial	C92.0	
27	B01AX01	Defibrotide	80 mg/ml concentrate for solution for infusion -2.5 ml	C90, C81, C82, C83, C85, C91, C92, D46, D47, D61	
28	N05CM18	Dexmedetomidine	concentrate for solution for infusion 100 micrograms/ml - 2ml; 4 ml;	СЪГЛАСНО РУ	
29	L01XC16 L01FX06	Dinutuximab beta	4.5 mg/ml Concentrate for solution for infusion, 20 mg, 1 vial	от C76.0 до C76.5	
30	A16AB26	Eladocagene exuparvovec	2.8 x 10 ¹¹ vector genomes(vg)/0.5mL solution for infusion	E70.8	
31	A12BA30	Electrolytes - Potassium (different salts in combination)	8 mEq prolonged-release granules; 24 mEq prolonged-release granules	N13-N15	
32	B05XA31	Electrolytes in combination with other drugs	Concentrate for solution for infusion -10 ml	K90.8, K90.9, K91.2, K91.8, P78.3	Състав на 1 ampoule (10 ml): Zinc chloride - 10420 micrograms; Copper chloride dihydrate -1074 micrograms Manganese chloride tetrahydrate - 36.00 micrograms Sodium selenite 153.3 micrograms Potassium iodide 25.67 micrograms

33	L01XC23 L01FX08	Elotuzumab	powder for concentrate for solution for infusion 300 mg; powder for concentrate for solution for infusion 400 mg	C90.0	
34	J05AF10	Entecavir	0,05 mg/ml oral solution - 210 ml	B18; K 74.6	Entecavir като oral solution е предназначен за лечение на хронична HBV инфекция в детска възраст
35	B01AC16	Eptifibatide	0,75 mg/ml solution for injection - 100ml	I20, I21, I22, I23, I24, I25	
36	L01CB01	Etoposide	20 mg/ml concentrate for solution for infusion – 5 ml, 1 vial	C81.0, C81.1, C81.2, C81.3, C81.9, C82.0, C82.1, C82.2, C82.7, C82.9, C83.0, C83.1, C83.2, C83.3, C83.4, C83.5, C83.6, C83.7, C83.8, C84.0, C84.1, C83.4, C84.3, C84.4, C84.5, C85.1, C85.7, C85.9, C88.0, C88.9, C92.0; C62, C34, C81, C85, C92.0, C58, C56;	
37	B05BA02	Fat emulsions (fish oil triglycerides) injectable emulsion	Emulsion for infusion - 50 ml; 100 ml	K56.6, K65.0, K43.0, K80.4, T79.4, N20	
38	N03AX26	Fenfluramine	2.2 mg/ml Oral solution - 60 ml; 120 ml; 250 ml; 360 ml	G40.4, G40.6	
39	N01AH01 N02AB03	Fentanyl	50 mcg/ml solution for injection -2 ml x10; 50 mcg/ml solution for injection - 10 ml x 10	Съгласно РУ	
40	A07AA12	Fidaxomicin	200 mg film-coated tablets x 20	A04.7	

41	N03AX27	Ganaxolone	50mg/ml oral suspension – 110 ml (pack size: 1 bottle + 2 dosing syringes of 3 ml, 2 dosing syringes of 12 ml + 1 bottle adaptor) и (pack size: 5 bottle + 5 dosing syringes of 12 ml + 5 bottle adaptors)	G40.4	
42	J05AB06	Ganciclovir	500 mg powder for concentrate for solution for infusion - 1 vial; 5 vial	B25, B20.2, P35.1, Z94.4	
43	A16AX16	Givosiran	189 mg/ml, Solution for injection - 1ml	E 80.2	
44	A16AX09	Glycerol phenylbutyrate	1.1 g/ml oral liquid - 25 ml	E71.0, E71.1, E72.2	
45	C02AC02	Guanfacine	1 mg prolonged-release tablet; 2 mg prolonged-release tablet; 3 mg prolonged-release tablet; 4 mg prolonged-release tablet;	F90.0; F90.1; F90.8; F90.9	
46	J06BA01	Human normal immunoglobulin (SCIg)	200 mg/ml solution for subcutaneous injection - 5ml; 10 ml; 20 ml; 50 ml; 200 mg/ml solution for subcutaneous injection in pre-filled syringe - 5 ml, 10 ml, 20 ml	СЪГЛАСНО РУ	
47	H02AB09	Hydrocortison	5 mg modified-release tablets x 50; x 100 20 mg modified-release tablets x 50; x 100	E23.0	
48	H02AB09	Hydrocortison	5mg modified-release hard capsules x 50; x 100; 10 mg modified-release hard capsules x 50; x 100	E23.0, E25.0, E25.8, E27.1, E27.2, E27.3, E27.4, E31.0, E89.3, E25.0	
49	C01EB16	Ibuprofen	5 mg/ml solution for injection 2 ml x 4 ampoules	Q25.0	
50	N06BX13	Idebenon	150 mg film-coated tablets x 180	H47.2	

51	J06BA01	Immunoglobulins, normal human, for extravascular adm	100 mg/ml solution for infusion for subcutaneous use - 25 ml; 50 ml; 100 ml; 200 ml; 300 ml	Съгласно РУ	purity of at least 98% IgG
52	J06BA02	Immunoglobulins, normal human, for intravascular adm	100 mg/ml solution for infusion 25 ml; 50 ml; 100 ml; 200 ml; 400ml	Съгласно РУ	
53	J06BA02	Immunoglobulins, normal human, for intravascular adm.	50 mg/ml solution for infusion 10 ml, 20 ml, 50 ml, 100 ml, 200 ml, 400 ml, 500 ml	Съгласно РУ	
54	B06AC05	Lanadelumab	150 mg solution for injection in pre-filled syringe x 1	D84.1	
55	L01EX12	Larotrectinib	25 mg capsules x 60; 100 mg capsules x 60; 20 mg/ml oral solution 50 ml ; 20 mg/ml oral solution 100 ml	C40-41; C49.0; C64, C70-C72, C76.2	
56	L04AX04	Lenalidomide	2,5 mg hard capsules ; 7,5 mg hard capsules ;	C90.0, D46.0, C82	
57	R07AX30	Lumacaftor/Ivacaftor	75 mg/94 mg granules in sachet x 56	E84.0, E84.1, E84.8	
58	A16AX18	Lumasiran	94.5 mg/0.5 ml solution for injection	E74.8	
59	A05AX04	Maralixibat chloride	9.5 mg/mL oral solution	K76.8, Q44.7, Q44.2	
60	L01AA03	Melphalan	50 mg powder and solvent for concentrate for solution for injection/infusion ; 50 mg powder and solvent for concentrate for solution for infusion	C90, C81, C82, C83, C85, C91, C92, D46, D47, C74, C56, C50, Z94.9,	
61	L01BB02	Mercaptopurine	20 mg/ml oral suspension - 100 ml	C91.0	

62	J01DH52	Meropenem and vaborbactam	1 g + 1 g - Powder for concentrate for solution for infusion	N11.0, N11.1, N11.8, K65.0, J15.9, U83.7, N10, N11.9, K65	
63	V03AB17 V04CG05	Methylene blue = methylthioninium chloride	5 mg/ml solution for injection -10 ml; 2 ml	T 65.3, T65.8, T39.1 , T57.3	
64	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	
65	N05CD08	Midazolam	1 mg/ml solution for injection/infusion-10 ml; 2 ml	съгласно РУ	
66	L03AX15	Mifamurtide	4 mg powder for concentrate for dispersion for infusion	C40.0-C40.9, C41.0-C41.9, и C76.0-C76.5.	
67	L01DC03	Mitomycin	10 mg powder for solution for injection/infusion or intravesical use; 20 mg powder for solution for injection/infusion or intravesical use	C16, C50, C34, C25, C67	
68	L04AA06	Mycophenolic acid/mycophenolate mofetil	Powder for oral suspension 1000 mg/5ml	Z94.0, T86.1, Z94.4, T86.4, Z94.1, T86.2	
69	L04AA06	Mycophenolic acid/mycophenolate mofetil	500 mg powder for concentrate for solution for infusion - 4 vial	Z94.0, T86.1, Z94.4, T86.4, Z94.1, T86.2	
70	A16AX04	Nitisinone	4 mg/ml oral suspension – 90 ml	E70.2	
71	C01CA03	Norepinephrine	concentrate for solution for infusion 1 mg/ml -1ml; concentrate for solution for infusion 1 mg/ml -5 ml; concentrate for solution for infusion 1 mg/ml -10 ml;	I50.9, R57.1, R57.8, R57.9; Z94, I95, I05.0, I05.1, I05.2, I06.0, I06.1, I06.2, I07.0, I07.1, I07.2, I20.0, I20.8, I21.0, I21.1, I21.2, I21.3, I21.4, I21.9, I23.0, I23.2, I23.3, I23.4, I23.5, I23.6, I25.1, I25.2, I25.3, I25.4, I25.8, I33.0, I34.0, I34.1, I34.2, I35.0, I35.1, I35.2, I35.8, I36.1, I36.2, I42.1, I42.2, I51.3, I71.0, Q21.1, Q21.2	

72	A05AX05	Odevixibat	200 micrograms hard capsules 400 micrograms hard capsules 600 micrograms hard capsules 1200 micrograms hard capsules	K76.8, Q44.7, Q44.2	
73	N05AH03	Olanzapine	10 mg powder for solution for injection	F20; F30	
74	A16AB25	Olipudase alfa	4 mg powder for concentrate for solution for infusion; 20 mg powder for concentrate for solution for infusion	E75.2	
75	M09AX09	Onasemnogene abeparvovec-2 x 10 ¹³ vg/ml - Solution for infusion	2 x 10 ¹³ vg/ml - Solution for infusion 5.5 ml + 8.3 ml vial	G12.0, G12.1	
76	L01DB01	Pegylated liposomal Doxorubicin	2 mg/ml concentrate for solution for infusion	C90.0; C50, C56, C46	
77	N07XX11	Pitolisant	4.5 mg film-coated tablets	G47.4	
78	L04AX06	Pomalidomide	1 mg hard capsules; 2 mg hard capsules; 3 mg hard capsules;	C90.0	
79	J02AC04	Posaconazole	100 mg gastro-resistant tablets; 40 mg/ml oral suspension -105 ml bottle; 300 mg concentrate for solution for infusion-16.7 ml	СЪГЛАСНО РУ	
80	J05AX08	Raltegravir	25 mg chewable tablets ; 100 mg chewable tablets; 100 mg granules for oral suspension x 60 sachets	B20; B21; B22; B23; B24	
81	V03AF07	Rasburicase	1.5 mg/ml -1 ml Powder and solvent for concentrate for solution for infusion; 7,5 mg/5ml Powder and solvent for concentrate for solution for infusion	C91.0, C91.1, C92.0 ; C83.0, C83.3, C83.9, C83.7	
82	L04AA43	Ravulizumab	300 mg/3 ml concentrate for solution for infusion (100 mg/ml) 300 mg/3 ml concentrate for solution for infusion (10 mg/ml); 1100mg/1 mL concentrate for solution for infusion	D59.3, D59.5	
83	B06BD06	Regdanvimab	60 mg/ml concentrate for solution for infusion - 16 ml	U07.1	

84	J05AB16	Remdesivir	100 mg - Powder for concentrate for solution for infusion	U07.1	
85	L01EX19	Ripretinib	50 mg tablets x 90; x 30	C49.4	
86	N05AX08	Risperidone	75 mg - Powder and solvent for prolonged-release suspension for injection	F20	
87	B01AF01	Rivaroxaban	1 mg/ml granules for oral suspension - 2,625 g;5,25g	I80.1, I80.2, I82.8, I26, I48, Z95.2	
88	M03AC09	Rocuronium bromide	10mg/ml solution for injection/infusion - 5ml; 10 mg/ml Solution for injection - 10 ml	СЪГЛАСНО РУ	
89	A16AB14	Sebelipase alfa	2 mg/ml concentrate for solution for infusion - 10 ml	E75.5	
90	L04AC10	Secukinumab	75 mg solution for injection in pre-filled syringe x 1; x 3	L40.0	
91	L01EE04	Selumetinib	10 mg hard capsules; 25 mg hard capsules	C76.0, C76.1, C76.2, C76.3, C76.4, C76.5; Q85.0	
92	L04AC11	Siltuximab	100 mg powder for concentrante for solution for infusion; 400 mg powder for concentrante for solution for infusion	C85.7	
93	N07XX04	Sodium oxybate	500 mg/ml oral solution 180 ml	G47.4;G47.2	
94	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	МКБ К 91 покрива уврежданя на храносмилателните органи след медицински процедури, неклассифицирани и другаде

95	N03AX17	Stiripentol	250 mg hard capsules; 250 mg powder for oral suspension in sachet	G40.4, G40.	
96	V03AB35	Sugammadex	solution for injection 100 mg/ml - 5ml;	СЪГЛАСНО РУ	
97	L04AD02	Tacrolimus	5 mg/ml concentrate for solution for infusion - 1 ml x 10	Z94.0, T86.1, Z94.4, T86.4, Z94.1, T86.2	
98	N07XX08	Tafamidis	soft capsules 61 mg	E85.1, I43.8, E85.2, E85.4, E85.8	
99	V09HA03	Technetium (99mTc) antigranulocyte antibody	1 mg - Kit for radiopharmaceutical preparation	M86, M86.1, M86.2, M86.3, M86.4, M86.5, M86.6, M86.8, M86.9	
100	V09GA01	Technetium -99mTc Sestamibi	1 mg - Kit for radiopharmaceutical preparation	I20, D35.1, C75.0, C50	
101	A16AX08	Teduglutide	powder and solvent for solution for injection 1,25 mg, powder and solvent for solution for injection 5 mg	K91.2	
102	L01EX21	Tepotinib	225 mg film-coated tablets	C34	
103	L04AX02	Thalidomide	50 mg hard capsules x 28; 100 mg coated tablet x 30	C90.0	
104	L01AC01	Thiotepa	15 mg powder for concentrate for solution for infusion; 100 mg powder for concentrate for solution for infusion	СЪГЛАСНО РУ	
105	L01CX01	Trabectedin	0,25 mg powder for concentrate for solution for infusion; 1 mg powder for concentrate for solution for infusion	C49.9, C56	
106	L01AB02	Treosulfan	5 g powder for solution for infusion x 1; x 5	C90, C81, C82, C83, C85, C91, C92, D46, D47	

107	S01FA06	Tropicamide	5 mg/ml (0,5 %) eye drops solution x 10 ml	H00 - H59	
108	N03AG04	Vigabatrin	500 mg soluble tablets	G40.4, G40.6	
109	A16AX05	Zinc acetate dihydrate	50 mg hard capsules	E83.0	Чернодробна цироза в резултат на болестта на Wilson
110	M05BA08	Zoledronic acid	4mg/5ml concentrate for sol.for infusion	Съгласно РУ	