



РЕПУБЛИКА БЪЛГАРИЯ

Министерство на здравеопазването

Министър на здравеопазването

ЗАПОВЕД

17.6.2022 г.

X РД-01-253/17.06.2022 г.

документ,
регистриран от:
Signed by: Ivo Cvetanov 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 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-01-525/24.06.2021 г. допълнена със Заповед № РД-01-556/06.07.2021 г., РД-01-602/19.07.2021 г., РД-01-625/27.07.2021 г., РД-01-687/06.08.2021 г., РД-01-789/24.09.2021 г., РД-01-822/11.10.2021 г., РД-01-870/26.10.2021 г., РД-01-917/09.11.2021 г., РД-01-993/03.12.2021 г., РД-01-1001/07.12.2021 г., РД-01-1039/20.12.2021 г., РД-01-37/25.01.2022 г. и РД-01-131/10.03.2022 г., РД-01-182/26.04.2022 г., РД-01-224/06.06.2022 г. и РД-01-227/08.06.2022 г.

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

17.6.2022 г.

X Проф. Асена Сербезова

Проф. Асена Сербезова, дф
Министър на здравеопазването
Signed by: Asena Hristova Serbezova

СПИСЪК

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

Приложение към Заповед №

| № | АТС | INN | Лекарствена форма и количество на активното вещество | МКБ код | Допълнителна информация |
|----|---------|---|---|---|-------------------------|
| 1 | L01BB02 | 6-mercaptopurine | 20 mg/ml oral suspension -100 ml | C91.0 | |
| 2 | L04AC03 | Anakinra | 100 mg/ 0,67 ml solution for injection in pre-filled syringe | U07.1; J18.9 | |
| 3 | L01XX27 | Arsenic trioxide | 1mg/ml concentrate for solution for infusion - 10ml | C92.4 | |
| 4 | M03AC04 | Atracurium | 10 mg/ml solution for injection/infusion - 2.5 ml; 10 mg/ml solution for injection/infusion - 5 ml; | СЪГЛАСНО РУ | |
| 5 | A16AA06 | Betaine anhydrous | 1 g oral powder - 180 g | E71.2 | |
| 6 | L01DC01 | Bleomycin | 15 000 IU powder for solution for injection (Liophilized powder for injection) | C00-C14; C15; C30; C32; C38; C51; C53; C60; C62; C63; C78.2; C78.6; C81 | |
| 7 | N01BB01 | Bupivacaine | 5 mg/ml solution for injection- 20 ml | СЪГЛАСНО РУ | |
| 8 | M05BX05 | Burosumab | 10 mg/ml solution for injection- 1ml; 20 mg/ml solution for injection- 1ml; 30 mg/ml solution for injection- 1ml; | E83.3 | |
| 9 | L01AB01 | Busulfan | 6 mg/ml concentrate for solution for infusion - 10ml | Z94.8; C90.0; C91; C92; C93; C81; C82; C83; C84; C85; D46; D47 | |
| 10 | B06AC01 | C1 inhibitor (human) c1-inhibitor, plasma derived | Powder and solvent for solution for injection 100 IU/ml- 5 ml; | D84.1 | |

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|----|----------------|---|--|---|--|
| 11 | B06AC01 | C1-esterase inhibitor (human) subcutaneous c1-inhibitor, plasma derived | Powder and solvent for solution for injection 3000 IU; Powder and solvent for solution for injection 2000 IU | D84.1 | |
| 12 | A16AA05 | Carglumic acid | 200 mg dispersible tablets | E71.0, E71.1, E72.2 | |
| 13 | не е установен | Casirivimab/imdevimab | 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); 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) | U07.1 | |
| 14 | J02AX04 | Caspofungin | 50 mg powder for concentrate for solution for infusion; 70 mg powder for concentrate for solution for infusion | B37; B44; | |
| 15 | B02BD11 | Catridecacog - recombinant coagulation factor XIII | Powder and solvent for solution for injection 2500 IU | D68.2 | |
| 16 | L01AA01 | Cyclophosphamide | 50 mg coated tablets 50 mg | N0.0-N5.8; N08.2-N08.5; D69.0; M30.2; M31.3; M32.1;M32.8;M33.0; M33.2 | |
| 17 | B01AX01 | Defibrotide | 80 mg/ml concentrate for solution for infusion -2,5 ml | C81; C82; C83; C84; C85; C90; C91; C92; C93; C94; Z94.8; D46; D47; D56; D57; D60; D61; D69; D71; D72; D81; D82 | |

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|----|---------|--|--|--|--|
| 18 | N05CM18 | Dexmedetomidine | 100 mcg/ml - 2ml concentrate for solution for infusion 100 mcg/ml - 2ml; 100 mcg/ml concentrate for solution for infusion - 10ml | СЪГЛАСНО РУ | |
| 19 | L01XC16 | Dinutuximab beta | 20 mg/4,5 ml concentrate for solution for infusion | C76.0-C76.3 | |
| 20 | J01AA02 | Doxycycline | 20 mg/ml solution for injection/infusion - 5ml | A00; A01; A06; A07.1;A21; A50-64; A79; A77; A78; A69.2; A70-74; A77.1; A78; J16; L70 | |
| 21 | L04AA25 | Eculizumab | 300 mg concentrate for solution for infusion 300 mg | N0.0-N5.8; N08.2-N08.5; D59.3, M31.1, N04.5 | |
| 22 | B01AB05 | Enoxaparin | 2 000 IU (20 mg)/0,2 ml solution for injection in pre-filled syringe; 6 000 IU (60 mg)/0.6 ml solution for injection in pre-filled syringes 10 000 IU (100 mg)/1 ml solution for injection in pre-filled syringe | N0.0-N5.8; N08.2-N08.5 | |
| 23 | J05AF10 | Entecavir | 0.05mg/ml oral solution - 210 ml | B18; B18.1; B16.9; | |
| 24 | B05BA02 | Fat emulsions (fish oil triglycerides) | injectable emulsion 10 g/100 ml - 50 ml; 100 ml | K90.8, K90.9; K91.2, K91.8; P78.3 | |
| 25 | N03AX26 | Fenfluramine | 2.2 mg/ml Oral solution, 60ml; 120ml; 250ml; 360ml | G40.6 | |
| 26 | N03AX26 | Fenfluramine | 2.2mg/mL oral solution - 60ml; 120ml; 250ml; 360ml | G40.6 | |
| 27 | N01AH01 | Fentanyl | 50 mcg/ml solution for injection - 2 ml; 50 mcg/ml solution for injection - 10 ml | СЪГЛАСНО РУ | |
| 28 | A07AA12 | Fidaxomicin | 200 mg film-coated tablets | A04.7 | |

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|----|---------|---|--|---|--|
| 29 | S01JA01 | Fluorescein | 100mg/ml solution for injection - 5 ml; | H30-H36 | |
| 30 | J05AB06 | Ganciclovir | 500 mg powder for concentrate for solution for infusion | B25.1; A87; P35.1; Z94.4 | |
| 31 | C02AC02 | Guanfacine hydrochloride | 1 mg prolonged-release tablets; 2 mg prolonged-release tablets; 3 mg prolonged-release tablets; 4 mg prolonged-release tablets; | E76.2 | |
| 32 | H04AA01 | Glucagon | 3 mg nasal powder | E10.2; E10.3; E10.4;E10.5; E10.7; E10.9 | |
| 33 | J06BA02 | Human normal immunoglobulin for intravascular use (immunoglobulins, normal human, for intravascular adm.) | 100 mg/ml solution for infusion - 10 ml; 20 ml; 25 ml; 50 ml; 100 ml | A02; A03; A04; A05; A 08; A09; A86.0; A86.0; A39.1; G00.2; G00.3; G00.0; G01; N0.0-N5.8; N08.2-N08.5; D69.0; M08.2; M30.3; M32.1; M32.8; M33.0; M33.2; M34.0; M35.8 | |
| 34 | H02AB09 | Hydrocortisone | 2 mg granules in capsules for opening | E23.0; E25.0; E27.1; 27.2; E27.3 E27.4; E31 | |
| 35 | H02AB09 | Hydrocortisone | 100 mg powder for solution for injection/ infusion | E23.0; E25.0; E27.1; E27.2; E27.3; E27.4; | |
| 36 | H02AB09 | Hydrocortisone | 5 mg modified-release tablets | E23.0; E25.0; E25.8, E27.1, E27.2, E27.3, E27.4; | |
| 37 | C01EB16 | Ibuprofen | 5 mg/ml solution for injection - 2 ml | Q25.0 | |
| 38 | N06BX13 | Idebenone | 150mg film-coated tablets | H47.0 | |

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|----|---------|--|--|--|--|
| 39 | J06BA01 | Immunoglobulins, normal human, for extravascular adm (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 | A02; A03; A04; A05; A 08; A09; A86.0; A86.0; A39.1; B15; B16; B17; B19; G00.2; G00.3; G00.0; G01;N0.0-N5.8; N08.2-N08.5 | |
| 40 | J06BA01 | Immunoglobulins, normal human, for extravascular adm. (Human normal immunoglobulin (IVIg)) | 100mg/ml solution for infusion for subcutaneous use - 10ml ; 100 ml | A02; A03; A04; A05; A 08; A09; A86.0; A 86.0; A39.1; B15; B16;B17; B19; G00.2; G00.3; G00.0; G01; N0.0-N5.8; N08.2-N08.5 | |
| 41 | J06BA02 | Immunoglobulins, normal human, for intravascular adm. (Human normal immunoglobulin (IVIg)) | 50 mg/ml solution for infusion - 10 ml; 20 ml; 50 ml; 100 ml | A02; A03; A04; N0.0-N5.8; N08.2-N08.5 | |
| 42 | L03AB05 | Interferon alfa -2b | 3 000 000 IU/0,5 ml solution for injection/infusion s.c use | B18.1; B18.0; | |
| 43 | R07AX03 | Ivacaftor | 50 mg granules in sachet; 75 mg granules in sachet | E84.1; E84.9 | |
| 44 | L01EX12 | Larotrectinib | 20 mg/ml oral solution, 100ml | C07; C08; C34; C18; C20; C22; C43; C25; C40-C41; C49; C64; C50; C70-C73; C76.2; C80 | |
| 45 | L01XX02 | L-asparaginase | 10000 IU powder for solution for injection/infusion | C91.0; C83.7; C76.0-C76.3 | |
| 46 | J05AX18 | Letermovir | Solution for injection 480 mg/24 ml. | B25 | |
| 47 | C01CX08 | Levosimendan | 2,5 mg/ml concentrate for solution for infusion - 5 ml | I50; I50.0; I50.1; I50.9 | |

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| 48 | N05BA06 | Lorazepam | 4mg/ml solution for injection/infusion | G40.6, G41.0 | |
| 49 | A16AX18 | Lumasiran | 94,5 mg/0,5 ml solution for injection | E72.53; | |
| 50 | L01AA03 | Melphalan | 50 mg powder and solvent for concentrate for solution for injection/infusion | E85; C56; Z94.8; C90.0 | |
| 51 | L01AA03 | Melphalan | 50 mg powder and solvent for concentrate for solution for injection/infusion | E85; C56; Z94.8; C90.0 | |
| 52 | A16AA07 | Metreleptin | 5,8 mg powder for solution for injections | E88.1 | |
| 53 | C01BB02 | Mexiletine | 167 mg hard capsules 167 mg x 30; 50; 100; 200 | I47.2; I49.3; I45.81 | |
| 54 | N05CD08 | Midazolam | 1mg/1ml solution for injection/infusion - 5ml;10 ml; 25 ml; 50 ml; 100 ml ; 2mg/ml solution for injection/infusion - 50 ml; 5mg/ml solution for injection/infusion - 10 ml | Съгласно РУ | |
| 55 | L04AA06 | Mycophenolic acid/mycophenolate mofetil | 500 mg powder for concentrate for solution for infusion | Z94.0; T86.1; Z94.4; T86.4; Z94.1; T86.2; Z94.8; K75.4; N0.0-N05.8; N08.2-N08.5; D61.3; C81; C82; C83; C84; C85; C90; C91; C92; C93; C94; D46; D47; D56; D57; D60; D61; D69; D71; D72; D81; D82; M32.1; M32.8; | |

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|----|---------|---|--|--|---|
| 56 | L04AA06 | Mycophenolic acid/mycophenolate mofetil | 1 g/5 ml powder for oral suspension | Z94.0; T86.1; Z94.4; T86.4; Z94.1; T86.2; Z94.8; N00.0- N5.8; N08.2- N08.5; D61.3; C81; C82; C83; C84; C85; C90; C91; C92; C93; C94; D46; D47; D56; D57; D60; D61; D69; D71; D72; D81; D82; M32.1; M32.8; | |
| 57 | A16AX04 | Nitisinone | 4 mg/ml oral suspension- 90 ml | E70.2 | |
| 58 | C01CA03 | Norepinephrine | 1 mg/ml concentrate for solution for infusion -1ml; 1 mg/ml concentrate for solution for infusion -5 ml; 1 mg/ml concentrate for solution for infusion -10 ml; | СЪГЛАСНО РУ | |
| 59 | A05AX05 | Odevixibat | 200 µg hard capsules x 30 ; 400 µg hard capsules x 30; 600 µg hard capsules x 30; 1200 µg hard capsules x 30 | K76.8; Q44.7; Q44.2 | |
| 60 | M09AX09 | Onasemnogene abeparvovec | 2×10^{13} vector genomes/ml solution for infusion vial 5.5 ml + vial 8.3 ml | G12.0; G12.1; | За лечение на: - пациенти с 5q спинална мускулна атрофия(СМА) с биалелна мутация в гена SMN1 и клинична диагноза за СМА тип 1, или - пациенти с 5q СМА с биалелна мутация в гена SMN1 и до 3 копия на гена SMN2. Индикациите са ограничени за пациенти до 2 годишна възраст. |
| 61 | N07XX11 | Pitolisant | 4.5 mg film-coated tablets x 30 tablets | G47.4 | |

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|----|------------------------|--|--|---|--|
| 62 | J02AC04 | Posaconazol | 40 mg/ml oral suspension | B37;B38;B39; B40;B41;B44; B45; B46; B48.7; B48.8 | |
| 63 | A12BA30 | Potassium citrate/Potassium hydrogen carbonate | 8 mEq prolonged-release granules; 24 mEq prolonged-release granules | N15.8 | |
| 64 | S01LA04 | Ranibizumab | 10 mg/ml solution for injection | H35.3; H36.0; H34.8; H44.2 | |
| 65 | все още не е определен | Regdanvimab | 60 mg/ml concentrate for solution for infusion - 16ml | U07.1 | |
| 66 | J05AB16 | Remdesevir | 100 mg powder for concentrate for solution for infusion 100 mg; | U07.1 | |
| 67 | M03AC09 | Rocuronium bromide | 10 mg/ml solution for injection/infusion - 5 ml; 10ml; 20 ml | СЪГЛАСНО РУ | |
| 68 | V10BX02 | Samarium(153Sm) lexidronam pentasodium | 1.3 GBq/ml solution for injection | СЪГЛАСНО РУ | |
| 69 | A16AB14 | Sebelipase alfa | 2 mg/ml concentrate for solution for infusion | E75.5 | |
| 70 | L01EX22 | Selpercatinib | 40 mg hard capsules x 56; 80 mg hard capsules x 56 | C34; C73 | |
| 71 | N07XX04 | Sodium oxybate | 500 mg/ml oral solution- 180ml | G47.4; | |
| 72 | N03AX17 | Stiripentol | 250 mg hard capsules | G40.6 | |
| 73 | N07XX08 | Tafamidis | 61 mg soft capsules | E85.2; E85.4; E85.8 | |
| 74 | V09GA01 | Techenitium (99mTc) sestambi | 1 mg kit for radiopharmaceuticals preparation | I20; D35.1; C75.0; C50 | |

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|----|---------|------------------------|---|--|--|
| 75 | A16AX08 | Teduglutide | 1,25 mg powder and solvent for solution for injection; 5 mg powder and solvent for solution for injection | K90.9; K91.2 | |
| 76 | L01AC01 | Thiotepa | 15 mg powder for concentrate for solution for infusion ; 100 mg powder for concentrate for solution for infusion | Z94.8; C90.0; C91; C92; C93; C81; C82; C83; C84; C85; D46; D47 | |
| 77 | S01FA06 | Tropicamide | 5 mg/ml eye drops solution - 10 ml | H00-H59 | |
| 78 | L01CA02 | Vincristine | 1mg/ml solution for injection - 1ml | C00-C14; C30- C32; C34; C49; C50; C71; C76.3; C90; C91; C96; C81; C82; C83; C84; C85; C88 | |
| 79 | A16AX05 | Zinc acetate dihydrate | 50 mg hard capsules | E83.0 | |