

Popis novoodobrenih lijekova od 01.04.2018. do 30.04.2018. godine/The list of newly approved medicinal products in April 2018

| Redni broj/No. | Naziv lijeka/Name | Broj odobrenja/Marketing Authorisation Number | Naziv djelatne tvari (INN, ostalo)/Active Substance | Proizvođač/Manufacturer | Nositelj odobrenja/Marketing Authorisation Holder |
|-----------------------|---|--|--|---|---|
| 1 | Amlodipin/Valsartan Genericon 10 mg/160 mg filmom obložene tablete | HR-H-542525534 | amlodipinum, valsartanum | Genericon Pharma Gesellschaft m.b.H., Graz, Austrija; Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska | Genericon Pharma Gesellschaft m.b.H., Hafnerstraße 211, Graz, Austrija |
| 2 | Amlodipin/Valsartan Genericon 5 mg/160 mg filmom obložene tablete | HR-H-814957492 | amlodipinum, valsartanum | Genericon Pharma Gesellschaft m.b.H., Graz, Austrija; Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska | Genericon Pharma Gesellschaft m.b.H., Hafnerstraße 211, Graz, Austrija |
| 3 | Amlodipin/Valsartan Genericon 5 mg/80 mg filmom obložene tablete | HR-H-152089428 | amlodipinum, valsartanum | Genericon Pharma Gesellschaft m.b.H., Graz, Austrija; Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska | Genericon Pharma Gesellschaft m.b.H., Hafnerstraße 211, Graz, Austrija |
| 4 | Fusamix Easyhaler 50 mikrograma + 250 mikrograma u jednoj dozi, prašak inhalata | HR-H-684471832 | salmeterolum, fluticasonum | Orion Corporation, Orion Pharma, Espoo, Finska | Orion Corporation, Orion Pharma, Orionintie 1, Espoo, Finska |
| 5 | Fusamix Easyhaler 50 mikrograma + 500 mikrograma u jednoj dozi, prašak inhalata | HR-H-554692844 | salmeterolum, fluticasonum | Orion Corporation, Orion Pharma, Espoo, Finska | Orion Corporation, Orion Pharma, Orionintie 1, Espoo, Finska |
| 6 | Lenalidomid Alvogen 10 mg tvrde kapsule | HR-H-760591329 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |

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| 7 | Lenalidomid Alvogen 15 mg tvrde kapsule | HR-H-834213906 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |
| 8 | Lenalidomid Alvogen 2,5 mg tvrde kapsule | HR-H-821309332 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |
| 9 | Lenalidomid Alvogen 20 mg tvrde kapsule | HR-H-668924151 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |
| 10 | Lenalidomid Alvogen 25 mg tvrde kapsule | HR-H-404688904 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |
| 11 | Lenalidomid Alvogen 5 mg tvrde kapsule | HR-H-456859816 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |
| 12 | Lenalidomid Alvogen 7,5 mg tvrde kapsule | HR-H-801701518 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Alvogen Malta Operations (ROW) Ltd., Malta Life Sciences Park, Building 1, Level 4, Sir Temi Zammit Buildings, San Gwann, Malta |
| 13 | Lenalidomid Labormed 10 mg tvrde kapsule | HR-H-990622045 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |

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| 14 | Lenalidomid Labormed 15 mg tvrde kapsule | HR-H-282763367 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |
| 15 | Lenalidomid Labormed 2,5 mg tvrde kapsule | HR-H-979014018 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |
| 16 | Lenalidomid Labormed 20 mg tvrde kapsule | HR-H-267123905 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |
| 17 | Lenalidomid Labormed 25 mg tvrde kapsule | HR-H-840971855 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |
| 18 | Lenalidomid Labormed 5 mg tvrde kapsule | HR-H-680905084 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |
| 19 | Lenalidomid Labormed 7,5 mg tvrde kapsule | HR-H-576821061 | lenalidomidum | Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta; SC Labormed - Pharma SA, Bukurešt, Rumunjska | Labormed - Pharma S.A., 44B Theodor Pallady Blvd, 3rd District, Bucharest, Rumunjska |
| 20 | Oxygerolan 10 mg tablete s produljenim oslobađanjem | HR-H-307820705 | oxycodonum | G.L. Pharma GmbH, Lannach, Austrija | Alpha-Medical d.o.o., Dragutina Golika 36, Zagreb |
| 21 | Oxygerolan 20 mg tablete s produljenim oslobađanjem | HR-H-775337317 | oxycodonum | G.L. Pharma GmbH, Lannach, Austrija | Alpha-Medical d.o.o., Dragutina Golika 36, Zagreb |
| 22 | Oxygerolan 40 mg tablete s produljenim oslobađanjem | HR-H-595993902 | oxycodonum | G.L. Pharma GmbH, Lannach, Austrija | Alpha-Medical d.o.o., Dragutina Golika 36, Zagreb |
| 23 | Parnido 3 mg tablete s produljenim oslobađanjem | HR-H-872139233 | paliperidonum | Krka d.d., Novo mesto, Novo Mesto, Slovenija | Krka - farma d.o.o., Radnička cesta 48, Zagreb |

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| 24 | Parnido 6 mg tablete s produljenim oslobađanjem | HR-H-059977329 | paliperidonum | Krka d.d., Novo mesto, Novo Mesto, Slovenija | Krka - farma d.o.o., Radnička cesta 48, Zagreb |
| 25 | Parnido 9 mg tablete s produljenim oslobađanjem | HR-H-340571050 | paliperidonum | Krka d.d., Novo mesto, Novo Mesto, Slovenija | Krka - farma d.o.o., Radnička cesta 48, Zagreb |
| 26 | Saflutan 15 mikrograma/ml, kapi za oko, otopina | HR-H-485560365 | tafluprostum | Santen Oy, Tampere, Finska; Tubilux Pharma S.p.A., Pomezia (Roma), Italija | Santen Oy, Niittyhaankatu 20, Tampere, Finska |