

Popis novoodobrenih lijekova od 01.07.2019. do 31.07.2019. godine/The list of newly approved medicinal products in July 2019

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	Aerogal 5 mg filmom obložene tablete	HR-H-475567328	desloratadinum	Alterno AD d.o.o., PE, Ljubljana-Črnuče, Slovenija	Makpharm d.o.o., Folnegovičeva 1/A, Zagreb
2	Alsemol 50 mg filmom obložene tablete	HR-H-163501168	riluzolum	Glenmark Pharmaceuticals Europe Ltd., Croxley Green, Ujedinjeno Kraljevstvo; Glenmark Pharmaceuticals s.r.o., Vysoké Mýto, Češka	Makpharm d.o.o., Folnegovičeva 1/A, Zagreb
3	Imensa 1000 mg tablete	HR-H-149113055	paracetamolom	Aurex B.V., Baarn, Nizozemska	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
4	Imensa 500 mg tablete	HR-H-062875489	paracetamolom	Aurex B.V., Baarn, Nizozemska	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
5	Itulazax 12 SQ-Bet oralni liofilizat	HR-H-926972641	standardnizirani ekstrakt alergena peludi bijele breze	ALK-Abelló S.A., Madrid, Španjolska	ALK-Abelló A/S, Boge Allé 6-8, Horsholm, Danska
6	Kalijev jodid Marti Farm 65 mg tablete	HR-H-316006942	potassium iodide	Lek farmacevtska družba d.d., Ljubljana, Slovenija	Marti Farm d.o.o., Lašćinska cesta 40, Zagreb
7	Memovist 1,0 mmol/ml otopina za injekciju	HR-H-575122002	gadobutrolom	Bayer AG, Berlin, Njemačka	Bayer d.o.o., Radnička cesta 80, Zagreb
8	Memovist 1,0 mmol/ml otopina za injekciju u napunjenoj štrcaljki	HR-H-004792646	gadobutrolom	Bayer AG, Berlin, Njemačka	Bayer d.o.o., Radnička cesta 80, Zagreb
9	Metadon Alkaloid 1 mg/ml oralna otopina	HR-H-162557040	methadonum	Alkaloid - INT d.o.o., Ljubljana - Črnuče, Slovenija	Alkaloid - INT d.o.o., Šlandrova ulica 4, Ljubljana, Slovenija
10	Psotriol 50 mikrograma/g + 0,5 mg/g mast	HR-H-405066565	calcipotriolum, betamethasonum	mibe GmbH Arzneimittel, Brehna, Njemačka	Mibe pharmaceuticals d.o.o., Branitelja domovinskog rata 8, Ludbreg
11	Sunitinib Mylan 12,5 mg tvrde kapsule	HR-H-868042036	sunitinibum	Remedica Ltd., Limassol, Cipar; Pharmicare Premium Ltd., Birzebbugia, Malta	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska

12	Sunitinib Mylan 25 mg tvrde kapsule	HR-H-638233387	sunitinibum	Remedica Ltd., Limassol, Cipar; Pharmacare Premium Ltd., Birzebbugia, Malta	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
13	Sunitinib Mylan 37,5 mg tvrde kapsule	HR-H-063352486	sunitinibum	Remedica Ltd., Limassol, Cipar; Pharmacare Premium Ltd., Birzebbugia, Malta	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
14	Sunitinib Mylan 50 mg tvrde kapsule	HR-H-822672840	sunitinibum	Remedica Ltd., Limassol, Cipar; Pharmacare Premium Ltd., Birzebbugia, Malta	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
15	Sunitinib Sandoz 12,5 mg tvrde kapsule	HR-H-116999925	sunitinibum	Lek Pharmaceuticals d.d., Ljubljana, Slovenija; Remedica Ltd., Limassol, Cipar; Pharmacare Premium Ltd., Birzebbugia, Malta	Sandoz d.o.o., Maksimirska 120, Zagreb
16	Sunitinib Sandoz 25 mg tvrde kapsule	HR-H-326493637	sunitinibum	Lek Pharmaceuticals d.d., Ljubljana, Slovenija; Remedica Ltd., Limassol, Cipar; Pharmacare Premium Ltd., Birzebbugia, Malta	Sandoz d.o.o., Maksimirska 120, Zagreb
17	Sunitinib Sandoz 50 mg tvrde kapsule	HR-H-429632014	sunitinibum	Lek Pharmaceuticals d.d., Ljubljana, Slovenija; Remedica Ltd., Limassol, Cipar; Pharmacare Premium Ltd., Birzebbugia, Malta	Sandoz d.o.o., Maksimirska 120, Zagreb
18	TEMELOR 4 mg/ml otopina za injekciju	HR-H-641923492	lorazepamum	Medochemie Ltd., Agios Athanassios, Limassol, Cipar	Medochemie Iberia, S.A., Rua Jose Maria Nicolau, n 6, 7B, Sao Domingos de Benfica, Lisboa, Portugal
19	Vildagliptin Galenicum 50 mg tablete	HR-H-996710193	vildagliptinum	Galenicum Health S.L., Barcelona, Španjolska; SAG Manufacturing S.L.U., Madrid, Španjolska; Siegfried Malta Ltd, Hal Far, Malta	Galenicum Health S.L., Avda. Diagonal 123, planta 11, Barcelona, Španjolska