

Popis novoodobrenih lijekova od 01.01.2021. do 31.01.2021. godine/The list of newly approved medicinal products in January 2021

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	Amiodaronklorid Hameln 20 mg/ml otopina za infuziju	HR-H-475814519	amiodaronum	Hameln rds, Modra, Slovačka; Solupharm Pharmazeutische Erzeugnisse GmbH, Melsungen, Njemačka	hameln pharma gmbh, Inselstrasse 1, Hameln, Njemačka
2	Amlodipin/valsartan/HCT Zentiva 10 mg/160 mg/12,5 mg filmom obložene tablete	HR-H-371376765	amlodipinum, valsartanum, hydrochlorothiazidum	Genepharma S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmicare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
3	Amlodipin/valsartan/HCT Zentiva 10 mg/160 mg/25 mg filmom obložene tablete	HR-H-396712390	amlodipinum, valsartanum, hydrochlorothiazidum	Genepharma S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmicare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
4	Amlodipin/valsartan/HCT Zentiva 10 mg/320 mg/25 mg filmom obložene tablete	HR-H-990565250	amlodipinum, valsartanum, hydrochlorothiazidum	Genepharma S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmicare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
5	Amlodipin/valsartan/HCT Zentiva 5 mg/160 mg/12,5 mg filmom obložene tablete	HR-H-125671531	amlodipinum, valsartanum, hydrochlorothiazidum	Genepharma S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmicare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
6	Amlodipin/valsartan/HCT Zentiva 5 mg/160 mg/25 mg filmom obložene tablete	HR-H-462193150	amlodipinum, valsartanum, hydrochlorothiazidum	Genepharma S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmicare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka

7	Asbima HCT 10 mg/160 mg/12,5 mg filmom obložene tablete	HR-H-194453105	amlodipinum, hydrochlorothiazidum, valsartanum	Genepfarm S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
8	Asbima HCT 10 mg/160 mg/25 mg filmom obložene tablete	HR-H-770535465	amlodipinum, hydrochlorothiazidum, valsartanum	Genepfarm S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
9	Asbima HCT 10 mg/320 mg/25 mg filmom obložene tablete	HR-H-368653142	amlodipinum, hydrochlorothiazidum, valsartanum	Genepfarm S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
10	Asbima HCT 5 mg/160 mg/12,5 mg filmom obložene tablete	HR-H-967490182	amlodipinum, hydrochlorothiazidum, valsartanum	Genepfarm S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
11	Asbima HCT 5 mg/160 mg/25 mg filmom obložene tablete	HR-H-015236944	amlodipinum, hydrochlorothiazidum, valsartanum	Genepfarm S.A., Pallini Attiki, Grčka; Pharmadox Healthcare Limited, Paola PLA, Malta; Pharmacare Premium Ltd., Birzebbugia, Malta	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka
12	Eslikarbazepinacetat Accord 200 mg tablete	HR-H-630538820	eslicarbazepinum	Laboratori Fundacio Dau, Barcelona, Španjolska; Accord Healthcare Limited, Middlesex, Ujedinjeno Kraljevstvo; Pharmadox Healthcare Limited, Paola, Malta; Accord Healthcare Polska Sp. z o.o., Pabianice, Poljska	Accord Healthcare Polska Sp. z o.o., Ul. Tasmowa 7, Mazowieckie, Varšava

13	Eslikarbazepinacetat Accord 800 mg tablete	HR-H-675977134	eslicarbazepinum	Laboratori Fundacio Dau, Barcelona, Španjolska; Accord Healthcare Limited, Middlesex, Ujedinjeno Kraljevstvo; Pharmadox Healthcare Limited, Paola, Malta; Accord Healthcare Polska Sp. z o.o., Pabianice, Poljska	Accord Healthcare Polska Sp. z o.o., Ul. Tasmowa 7, Mazowieckie, Varšava, Poljska
14	Igzelym 60 mg filmom obložene tablete	HR-H-832223866	ticagrelorum	PharOS MT Ltd, Birzebbugia, Malta	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
15	Igzelym 90 mg filmom obložene tablete	HR-H-068420536	ticagrelorum	PharOS MT Ltd, Birzebbugia, Malta	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
16	Lantan Mylan 1000 mg tablete za žvakanje	HR-H-928920938	lanthanum	Mylan UK Healthcare Limited, Potter Bar, Ujedinjeno Kraljevstvo; Mylan Germany GmbH , Bad Homburg, Hesse, Njemačka; Mylan Hungary Kft, Komárom, Mađarska; McDermott Laboratories Limited, t/a Gerard Laboratories, Dublin 13, Irska	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
17	Lantan Mylan 500 mg tablete za žvakanje	HR-H-708522317	lanthanum	Mylan UK Healthcare Limited, Potter Bar, Ujedinjeno Kraljevstvo; Mylan Germany GmbH , Bad Homburg, Hesse, Njemačka; Mylan Hungary Kft, Komárom, Mađarska; McDermott Laboratories Limited, t/a Gerard Laboratories, Dublin 13, Irska	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska

18	Lantan Mylan 750 mg tablete za žvakanje	HR-H-796159421	lanthanum	Mylan UK Healthcare Limited, Potter Bar, Ujedinjeno Kraljevstvo; Mylan Germany GmbH, Bad Homburg, Hesse, Njemačka; Mylan Hungary Kft, Komárom, Mađarska; McDermott Laboratories Limited, t/a Gerard Laboratories, Dublin 13, Irska	Mylan Ireland Limited, Unit 35/36 Grange Parade, Baldoyle Industrial Estate, Dublin 13, Irska
19	Losmorid 100 mg filmom obložene tablete	HR-H-848414378	lacosamidum	Alkaloid - INT d.o.o., Ljubljana - Črnuče, Slovenija	Alkaloid - INT d.o.o., Šlandrova ulica 4, Ljubljana - Črnuče, Slovenija
20	Losmorid 150 mg filmom obložene tablete	HR-H-431968714	lacosamidum	Alkaloid - INT d.o.o., Ljubljana - Črnuče, Slovenija	Alkaloid - INT d.o.o., Šlandrova ulica 4, Ljubljana - Črnuče, Slovenija
21	Losmorid 200 mg filmom obložene tablete	HR-H-257195744	lacosamidum	Alkaloid - INT d.o.o., Ljubljana - Črnuče, Slovenija	Alkaloid - INT d.o.o., Šlandrova ulica 4, Ljubljana - Črnuče, Slovenija
22	Losmorid 50 mg filmom obložene tablete	HR-H-394155128	lacosamidum	Alkaloid - INT d.o.o., Ljubljana - Črnuče, Slovenija	Alkaloid - INT d.o.o., Šlandrova ulica 4, Ljubljana - Črnuče, Slovenija
23	Memantin Grindeks 10 mg filmom obložene tablete	HR-H-073848955	memantinum	AS Grindeks, Riga, Latvija	AS Grindeks, Krustpils iela 53, Riga, Latvija
24	Rivaroksaban Pliva 10 mg filmom obložene tablete	HR-H-821194254	rivaroxabanum	Teva UK Ltd., Eastbourne, Ujedinjeno Kraljevstvo; Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska; Teva Pharma B.V., Haarlem, Nizozemska	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb, Hrvatska
25	Rivaroksaban Pliva 15 mg filmom obložene tablete	HR-H-727893287	rivaroxabanum	Teva UK Ltd., Eastbourne, Ujedinjeno Kraljevstvo; Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska; Teva Pharma B.V., Haarlem, Nizozemska	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb, Hrvatska
26	Rivaroksaban Pliva 20 mg filmom obložene tablete	HR-H-778216192	rivaroxabanum	Teva UK Ltd., Eastbourne, Ujedinjeno Kraljevstvo; Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska; Teva Pharma B.V., Haarlem, Nizozemska	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb, Hrvatska

27	Serynox 50%/50% V/V medicinski plin, stlačen	HR-H-713914145	dinitrogenii oxidum, oxygenium	Messer France, Saint-Georges-d'Espéranche, Francuska	Messer Croatia Plin d.o.o., Industrijska 1, Zaprešić, Hrvatska
28	Tresuvi 1 mg/ml otopina za infuziju	HR-H-579967087	treprostiniolum	Amomed Pharma GmbH, Beč, Austrija	Orpha-Devel Handels und Vertriebs GmbH, Wintergasse 85/1B, Purkersdorf, Austrija
29	Tresuvi 10 mg/ml otopina za infuziju	HR-H-816101187	treprostiniolum	Amomed Pharma GmbH, Beč, Austrija	Orpha-Devel Handels und Vertriebs GmbH, Wintergasse 85/1B, Purkersdorf, Austrija
30	Tresuvi 2,5 mg/ml otopina za infuziju	HR-H-745171074	treprostiniolum	Amomed Pharma GmbH, Beč, Austrija	Orpha-Devel Handels und Vertriebs GmbH, Wintergasse 85/1B, Purkersdorf, Austrija
31	Tresuvi 5 mg/ml otopina za infuziju	HR-H-777980453	treprostiniolum	Amomed Pharma GmbH, Beč, Austrija	Orpha-Devel Handels und Vertriebs GmbH, Wintergasse 85/1B, Purkersdorf, Austrija
32	Vainas 10 mg/160 mg filmom obložene tablete	HR-H-510800699	amlodipinum, valsartanum	Belupo lijekovi i kozmetika d.d., Koprivnica, Hrvatska	Belupo lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Hrvatska
33	Vainas 5 mg/160 mg filmom obložene tablete	HR-H-399307358	amlodipinum, valsartanum	Belupo lijekovi i kozmetika d.d., Koprivnica, Hrvatska	Belupo lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Hrvatska
34	Vainas 5 mg/80 mg filmom obložene tablete	HR-H-642334220	amlodipinum, valsartanum	Belupo lijekovi i kozmetika d.d., Koprivnica, Hrvatska	Belupo lijekovi i kozmetika d.d., Ulica Danica 5, Koprivnica, Hrvatska
35	Visine 0,5 mg/ml kapi za oko, otopina	HR-H-481259776	tetryzolinum	Janssen Pharmaceutica N.V., Beerse, Belgija	Johnson & Johnson S.E. d.o.o., Oreškovićevo 6h, Zagreb, Hrvatska
36	Zassida 25 mg/ml prašak za suspenziju za injekciju	HR-H-083919150	azacitidinum	AqVida GmbH, Hamburg, Njemačka	Zentiva k.s., U Kabelovny 130, Dolni Mecholupy, Prag 10, Češka