

Popis novoodobrenih lijekova od 01.08.2015. do 31.08.2015. godine/The list of newly approved medicinal products in August 2015

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	Caminard 0,5 mg meke kapsule	HR-H-108467257	dutasteridum	Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska	Actavis Group PTC ehf, Reykjavikurvegi 76-78, Hafnarfjordur, Island
2	Egzysta 100 mg tvrde kapsule	HR-H-847280734	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
3	Egzysta 150 mg tvrde kapsule	HR-H-888807579	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
4	Egzysta 200 mg tvrde kapsule	HR-H-639380681	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
5	Egzysta 225 mg tvrde kapsule	HR-H-593086259	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
6	Egzysta 25 mg tvrde kapsule	HR-H-263654766	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
7	Egzysta 300 mg tvrde kapsule	HR-H-232110752	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
8	Egzysta 50 mg tvrde kapsule	HR-H-745496729	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zakłady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska

9	Egzysta 75 mg tvrde kapsule	HR-H-629149768	pregabalinum	Adamed Sp. z o.o., Czosnów, Poljska; Pabianickie Zaklady Farmaceutyczne Polfa S.A., Pabianice, Poljska	Adamed Sp. z o.o., Pienków 149, Czosnów, Poljska
10	Kodein/paracetamol Actavis 30 mg/500 mg filmom obložene tablete	HR-H-598712768	codeini phosphas hemihydricus, paracetamolium	Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska; Actavis ehf., Hafnarfjordur, Island	Actavis Group PTC ehf, Reykjavikurvegi 76-78, Hafnarfjordur, Island
11	Kodein/paracetamol Actavis 60 mg/1000 mg filmom obložene tablete	HR-H-660564683	codeini phosphas hemihydricus, paracetamolium	Balkanpharma - Dupnitsa AD, Dupnitsa, Bugarska; Actavis ehf., Hafnarfjordur, Island	Actavis Group PTC ehf, Reykjavikurvegi 76-78, Hafnarfjordur, Island
12	Lipertance 10 mg/5 mg/5 mg filmom obložene tablete	HR-H-348161595	atorvastatinum, amlodipinum, perindoprilum	Les Laboratoires Servier Industrie, Gidy, Francuska; Egis Pharmaceuticals Public Limited Company (PLC), Kormend, Mađarska; Servier (Ireland) Industries Ltd., Arklow, Irska; Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Varšava, Poljska	Servier Pharma d.o.o., Tuškanova 37, Zagreb
13	Lipertance 20 mg/10 mg/10 mg filmom obložene tablete	HR-H-191076644	atorvastatinum, amlodipinum, perindoprilum	Les Laboratoires Servier Industrie, Gidy, Francuska; Egis Pharmaceuticals Public Limited Company (PLC), Kormend, Mađarska; Servier (Ireland) Industries Ltd., Arklow, Irska; Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Varšava, Poljska	Servier Pharma d.o.o., Tuškanova 37, Zagreb

14	Lipertance 20 mg/10 mg/5 mg filmom obložene tablete	HR-H-818657827	atorvastatinum, amlodipinum, perindoprilum	Les Laboratoires Servier Industrie, Gidy, Francuska; Egis Pharmaceuticals Public Limited Company (PLC), Kormend, Mađarska; Servier (Ireland) Industries Ltd., Arklow, Irska; Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Varšava, Poljska	Servier Pharma d.o.o., Tuškanova 37, Zagreb
15	Lipertance 20 mg/5 mg/5 mg filmom obložene tablete	HR-H-295218551	atorvastatinum, amlodipinum, perindoprilum	Les Laboratoires Servier Industrie, Gidy, Francuska; Egis Pharmaceuticals Public Limited Company (PLC), Kormend, Mađarska; Servier (Ireland) Industries Ltd., Arklow, Irska; Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Varšava, Poljska	Servier Pharma d.o.o., Tuškanova 37, Zagreb
16	Lipertance 40 mg/10 mg/10 mg filmom obložene tablete	HR-H-236429430	atorvastatinum, amlodipinum, perindoprilum	Les Laboratoires Servier Industrie, Gidy, Francuska; Egis Pharmaceuticals Public Limited Company (PLC), Kormend, Mađarska; Servier (Ireland) Industries Ltd., Arklow, Irska; Anpharm Przedsiębiorstwo Farmaceutyczne S.A., Varšava, Poljska	Servier Pharma d.o.o., Tuškanova 37, Zagreb
17	Lopinavir/Ritonavir Sandoz 200 mg/50 mg filmom obložene tablete	HR-H-504948082	lopinavirum, ritonavirum	Salutas Pharma GmbH, Barleben, Njemačka	Sandoz d.o.o., Maksimirska 120, Zagreb
18	Nimedol 0,4 mg sublingvalne tablete	HR-H-221990733	buprenorphinum	Merckle GmbH, Blaubeuren, Njemačka; Actavis ehf., Hafnarfjordur, Island	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb

19	Nimedol 2 mg sublingvalne tablete	HR-H-056604005	buprenorphinum	Merckle GmbH, Blaubeuren, Njemačka; Actavis ehf., Hafnarfjordur, Island	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb
20	Nimedol 8 mg sublingvalne tablete	HR-H-481991441	buprenorphinum	Merckle GmbH, Blaubeuren, Njemačka; Actavis ehf., Hafnarfjordur, Island	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb
21	Tenofovirdizoproksil Pliva 245 mg filmom obložene tablete	HR-H-373118482	tenofovirum	Merckle GmbH, Ulm, Njemačka; Teva Operations Poland Sp. z o.o., Kutno, Poljska; Teva Pharmaceutical Works Private Limited Company, Debrecen, Mađarska; Teva UK Ltd., East Sussex, Ujedinjeno Kraljevstvo; Teva Operations Poland Sp. z o.o., Krakow, Poljska; Pharmachemie B.V., Haarlem, Nizozemska; Teva Pharma B.V., Haarlem, Nizozemska	Pliva Hrvatska d.o.o., Prilaz baruna Filipovića 25, Zagreb