21 March 2018
EMA/267099/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: ezetimibe / rosuvastatin

Procedure no.: PSUSA/00010271/201707

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Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ridutrin 10 mg/10 mg capsule, hard	NL/H/3017/001/DC	RVG 114008	EGIS PHARMACEUTICALS PLC	NL
Ridutrin 20 mg/10 mg capsule, hard	NL/H/3017/002/DC	RVG 114009	EGIS PHARMACEUTICALS PLC	NL
Ridutrin 40 mg/10 mg capsule, hard	NL/H/3017/003/DC	RVG 114010	EGIS PHARMACEUTICALS PLC	NL
Lipocomb 10 mg/10 mg cápsulas duras	NL/H/3017/001-003/DC	79053	EGIS PHARMACEUTICALS PLC	ES
Lipocomb 20 mg/10 mg cápsulas duras	NL/H/3017/001-003/DC	79051	EGIS PHARMACEUTICALS PLC	ES
Lipocomb 40 mg/10 mg cápsulas duras	NL/H/3017/001-003/DC	79052	EGIS PHARMACEUTICALS PLC	ES
Zenon 10 mg/20 mg filmom obalené tablety	CZ/H/0455/002	31/0009/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/20 mg filmom obalené tablety	CZ/H/0455/002	31/0009/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/20 mg filmom obalené tablety	CZ/H/0455/002	31/0009/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/20 mg filmom obalené tablety	CZ/H/0455/002	31/0009/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/20 mg potahované tablety	CZ/H/0455/002	31/322/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/20 mg potahované tablety	CZ/H/0455/002	31/322/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/20 mg potahované tablety	CZ/H/0455/002	31/322/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/20 mg potahované tablety	CZ/H/0455/002	31/322/14-C	ZENTIVA, K.S.	CZ
Зенон 10 mg/20 mg филмирани таблетки	CZ/H/0455/002	20140378	ZENTIVA, K.S.	BG
Зенон 10 mg/20 mg филмирани таблетки	CZ/H/0455/002	20140378	ZENTIVA, K.S.	BG
Зенон 10 mg/20 mg филмирани таблетки	CZ/H/0455/002	20140378	ZENTIVA, K.S.	BG
Зенон 10 mg/20 mg филмирани таблетки	CZ/H/0455/002	20140378	ZENTIVA, K.S.	BG

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Suvezen, (10 mg + 20 mg), tabletki powlekane	CZ/H/0455/002	22278	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 20 mg), tabletki powlekane	CZ/H/0455/002	22278	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 20 mg), tabletki powlekane	CZ/H/0455/002	22278	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 20 mg), tabletki powlekane	CZ/H/0455/002	22278	ZENTIVA, K.S.	PL
Росулип плюс 10 mg/10 mg твърди капсули	NL/H/3007/001-003/DC	20140350	EGIS PHARMACEUTICALS PLC	BG
Росулип плюс 20 mg/10 mg твърди капсули	NL/H/3007/001-003/DC	20140351	EGIS PHARMACEUTICALS PLC	BG
Росулип плюс 40 mg/10 mg твърди капсули	NL/H/3007/001-003/DC	20140352	EGIS PHARMACEUTICALS PLC	BG
Rosulip 10 mg/10 mg cietās kapsulas	NL/H/3007/001-003/DC	14-0194	EGIS PHARMACEUTICALS PLC	LV
Rosulip 20 mg/10 mg cietās kapsulas	NL/H/3007/001-003/DC	14-0195	EGIS PHARMACEUTICALS PLC	LV
Rosulip 40 mg/10 mg cietās kapsulas	NL/H/3007/001-003/DC	14-0196	EGIS PHARMACEUTICALS PLC	LV
Rosulip Plus, 10 mg + 10 mg, kapsułki, twarde	NL/H/3007/001-003/DC	22082	EGIS PHARMACEUTICALS PLC	PL
Rosulip Plus, 20 mg + 10 mg, kapsułki, twarde	NL/H/3007/001-003/DC	22083	EGIS PHARMACEUTICALS PLC	PL
Rosulip Plus, 40 mg + 10 mg, kapsułki, twarde	NL/H/3007/001-003/DC	22084	EGIS PHARMACEUTICALS PLC	PL
Lipocomb 10 mg/10 mg kapsel, hård	NL/H/3007/001	49714	EGIS PHARMACEUTICALS PLC	SE
Lipocomb 20 mg/10 mg kapsel, hård	NL/H/3007/002	49715	EGIS PHARMACEUTICALS PLC	SE
Lipocomb 40 mg/10 mg kapsel, hård	NL/H/3007/003	49716	EGIS PHARMACEUTICALS PLC	SE
Ayadont 40 mg/10 mg capsule, hard	NL/H/3007/003/DC	RVG 114004	EGIS PHARMACEUTICALS PLC	NL

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ayadont 10 mg/10 mg capsule, hard	NL/H/3007/001/DC	RVG 114002	EGIS PHARMACEUTICALS PLC	NL
Ayadont 20 mg/10 mg capsule, hard	NL/H/3007/002/DC	RVG 114003	EGIS PHARMACEUTICALS PLC	NL
Delipid Plus 10 mg/10 mg kõvakapslid	NL/H/3007/001/DC	850014	EGIS PHARMACEUTICALS PLC	EE
Delipid Plus 20 mg/10 mg kõvakapslid	NL/H/3007/002/DC	849914	EGIS PHARMACEUTICALS PLC	EE
Delipid Plus 40 mg/10 mg kõvakapslid	NL/H/3007/003/DC	849814	EGIS PHARMACEUTICALS PLC	EE
Lipocomb 10 mg/10 mg trde kapsule	NL/H/3007/001/DC	H/16/02105/001-008	EGIS PHARMACEUTICALS PLC	SI
Lipocomb 20 mg/10 mg trde kapsule	NL/H/3007/002/DC	H/16/02105/009-016	EGIS PHARMACEUTICALS PLC	SI
Lipocomb 40 mg/10 mg trde kapsule	NL/H/3007/003/DC	H/16/02105/017-024	EGIS PHARMACEUTICALS PLC	SI
Ultrizor 10 mg/10 mg capsule rigide	NL/H/3007/001-003/DC	043496013,043496025,043496037, 043496049,043496052,043496064, 043496076,043496227	EGIS PHARMACEUTICALS PLC	IT
Ultrizor 20 mg/10 mg capsule rigide	NL/H/3007/001-003/DC	043496088,043496090,043496102, 043496114,043496126,043496138, 043496140,043496239	EGIS PHARMACEUTICALS PLC	IT
Ultrizor 40 mg/10 mg capsule rigide	NL/H/3007/001-003/DC	043496153,043496165,043496177, 043496189,043496191,043496203, 043496215,043496241	EGIS PHARMACEUTICALS PLC	IT
Viazet 10 mg/10 mg σκληρά καψάκια	NL/H/3007/001-003/DC	18439/5-3-2015	EGIS PHARMACEUTICALS PLC	GR
Viazet 20 mg/10 mg σκληρά καψάκια	NL/H/3007/001-003/DC	18440/5-3-2015	EGIS PHARMACEUTICALS PLC	GR
Viazet 40 mg/10 mg σκληρά καψάκια	NL/H/3007/001-003/DC	18441/5-3-2015	EGIS PHARMACEUTICALS PLC	GR
Lipocomb 10 mg/10 mg Hartkapseln	NL/H/3006/001/DC	135783	EGIS PHARMACEUTICALS PLC	AT
Lipocomb 20 mg/10 mg Hartkapseln	NL/H/3006/002/DC	135782	EGIS PHARMACEUTICALS PLC	AT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Lipocomb 40 mg/10 mg Hartkapseln	NL/H/3006/003/DC	135784	EGIS PHARMACEUTICALS PLC	AT
Viazet 10 mg/10 mg tvrdé tobolky	NL/H/3006/001-003/DC	31/354/14-C	EGIS PHARMACEUTICALS PLC	CZ
Viazet 20 mg/10 mg tvrdé tobolky	NL/H/3006/001-003/DC	31/355/14-C	EGIS PHARMACEUTICALS PLC	CZ
Viazet 40 mg/10 mg tvrdé tobolky	NL/H/3006/001-003/DC	31/356/14-C	EGIS PHARMACEUTICALS PLC	CZ
Lipocomb	NL/H/3006/001-003/DC	52921	EGIS PHARMACEUTICALS PLC	DK
Lipocomb	NL/H/3006/001-003/DC	52922	EGIS PHARMACEUTICALS PLC	DK
Lipocomb	NL/H/3006/001-003/DC	52923	EGIS PHARMACEUTICALS PLC	DK
Lipocomb 10 mg/10 mg hard capsules	NL/H/3006/001-003/DC	PA1470/004/001	EGIS PHARMACEUTICALS PLC	IE
Lipocomb 20 mg/10 mg hard capsules	NL/H/3006/001-003/DC	PA1470/004/002	EGIS PHARMACEUTICALS PLC	IE
Lipocomb 40 mg/10 mg hard capsules	NL/H/3006/001-003/DC	PA1470/004/003	EGIS PHARMACEUTICALS PLC	IE
Lipocomb 10 mg/10 mg capsule	NL/H/3006/001/DC	7026/2014/01-07	EGIS PHARMACEUTICALS PLC	RO
Lipocomb 20 mg/10 mg capsule	NL/H/3006/002/DC	7027/2014/01-07	EGIS PHARMACEUTICALS PLC	RO
Lipocomb 40 mg/10 mg capsule	NL/H/3006/003/DC	7028/2014/01-07	EGIS PHARMACEUTICALS PLC	RO
Viazet 10 mg/10 mg tvrdé kapsuly	NL/H/3006/001/DC	31/0289/14-S	EGIS PHARMACEUTICALS PLC	SK
Viazet 20 mg/10 mg tvrdé kapsuly	NL/H/3006/002/DC	31/0290/14-S	EGIS PHARMACEUTICALS PLC	SK
Viazet 40 mg/10 mg tvrdé kapsuly	NL/H/3006/003/DC	31/0291/14-S	EGIS PHARMACEUTICALS PLC	SK
Cholecomb 10 mg/10 mg, capsule hard	NL/H/3006/001/DC	RVG 114005	EGIS PHARMACEUTICALS PLC	NL

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Cholecomb 20 mg/10 mg, capsule hard	NL/H/3006/002/DC	RVG 114006	EGIS PHARMACEUTICALS PLC	NL
Cholecomb 40 mg/10 mg, capsule hard	NL/H/3006/003/DC	RVG 114007	EGIS PHARMACEUTICALS PLC	NL
Viazet gélules	NL/H/3006/001-003/DC	2014120440	EGIS PHARMACEUTICALS PLC	LU
Viazet gélules	NL/H/3006/001-003/DC	2014120441	EGIS PHARMACEUTICALS PLC	LU
Viazet gélules	NL/H/3006/001-003/DC	2014120442	EGIS PHARMACEUTICALS PLC	LU
Lipocomb 10 mg/10 mg harde kapsler	NL/H/3006/001-003/DC	13-9663	EGIS PHARMACEUTICALS PLC	NO
Lipocomb 20 mg/10 mg harde kapsler	NL/H/3006/001-003/DC	13-9664	EGIS PHARMACEUTICALS PLC	NO
Lipocomb 40 mg/10mg harde kapsler	NL/H/3006/001-003/DC	13-9665	EGIS PHARMACEUTICALS PLC	NO
Ultrizor, 10 mg/10 mg gélules	NL/H/3006/001-003	BE461733	EGIS PHARMACEUTICALS PLC	BE
Ultrizor, 20 mg/10 mg gélules	NL/H/3006/001-003	BE461742	EGIS PHARMACEUTICALS PLC	BE
Ultrizor 40 mg/10 mg gélules	NL/H/3006/001-003	BE461751	EGIS PHARMACEUTICALS PLC	BE
Zenon 10 mg/10 mg filmom obalené tablety	CZ/H/0455/001	31/0008/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/10 mg filmom obalené tablety	CZ/H/0455/001	31/0008/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/10 mg filmom obalené tablety	CZ/H/0455/001	31/0008/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/10 mg filmom obalené tablety	CZ/H/0455/001	31/0008/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/10 mg potahované tablety	CZ/H/0455/001	31/321/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/10 mg potahované tablety	CZ/H/0455/001	31/321/14-C	ZENTIVA, K.S.	CZ

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Zenon 10 mg/10 mg potahované tablety	CZ/H/0455/001	31/321/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/10 mg potahované tablety	CZ/H/0455/001	31/321/14-C	ZENTIVA, K.S.	CZ
Зенон 10 mg/10 mg филмирани таблетки	CZ/H/0455/001	20140377	ZENTIVA, K.S.	BG
Зенон 10 mg/10 mg филмирани таблетки	CZ/H/0455/001	20140377	ZENTIVA, K.S.	BG
Зенон 10 mg/10 mg филмирани таблетки	CZ/H/0455/001	20140377	ZENTIVA, K.S.	BG
Зенон 10 mg/10 mg филмирани таблетки	CZ/H/0455/001	20140377	ZENTIVA, K.S.	BG
Suvezen, (10 mg + 10 mg), tabletki powlekane	CZ/H/0455/001	22277	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 10 mg), tabletki powlekane	CZ/H/0455/001	22277	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 10 mg), tabletki powlekane	CZ/H/0455/001	22277	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 10 mg), tabletki powlekane	CZ/H/0455/001	22277	ZENTIVA, K.S.	PL
Zenon 10 mg/40 mg filmom obalené tablety	CZ/H/0455/003	31/0010/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/40 mg filmom obalené tablety	CZ/H/0455/003	31/0010/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/40 mg filmom obalené tablety	CZ/H/0455/003	31/0010/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/40 mg filmom obalené tablety	CZ/H/0455/003	31/0010/15-S	ZENTIVA, K.S.	SK
Zenon 10 mg/40 mg potahované tablety	CZ/H/0455/003	31/323/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/40 mg potahované tablety	CZ/H/0455/003	31/323/14-C	ZENTIVA, K.S.	CZ
Zenon 10 mg/40 mg potahované tablety	CZ/H/0455/003	31/323/14-C	ZENTIVA, K.S.	CZ

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Зенон 10 mg/40 mg филмирани таблетки	CZ/H/0455/003	20140379	ZENTIVA, K.S.	BG
Зенон 10 mg/40 mg филмирани таблетки	CZ/H/0455/003	20140379	ZENTIVA, K.S.	BG
Зенон 10 mg/40 mg филмирани таблетки	CZ/H/0455/003	20140379	ZENTIVA, K.S.	BG
Зенон 10 mg/40 mg филмирани таблетки	CZ/H/0455/003	20140379	ZENTIVA, K.S.	BG
Zenon 10 mg/40 mg potahované tablety	CZ/H/0455/003	31/323/14-C	ZENTIVA, K.S.	CZ
Suvezen, (10 mg + 40 mg), tabletki powlekane	CZ/H/0455/003	22279	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 40 mg), tabletki powlekane	CZ/H/0455/003	22279	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 40 mg), tabletki powlekane	CZ/H/0455/003	22279	ZENTIVA, K.S.	PL
Suvezen, (10 mg + 40 mg), tabletki powlekane	CZ/H/0455/003	22279	ZENTIVA, K.S.	PL
Viazet 10 mg/10 mg kemény kapszula	NL/H/3016/001/DC	OGYI-T-22700/01-03	EGIS PHARMACEUTICALS PLC	HU
Viazet 20 mg/10 mg kemény kapszula	NL/H/3016/002/DC	OGYI-T-22700/04-06	EGIS PHARMACEUTICALS PLC	HU
Viazet 40 mg/10 mg kemény kapszula	NL/H/3016/003/DC	OGYI-T-22700/07-09	EGIS PHARMACEUTICALS PLC	HU
Rosuvastatine/ezetimibe EGIS 10 mg/10 mg capsules, hard	NL/H/3016/001/DC	RVG 113986	EGIS PHARMACEUTICALS PLC	NL
Rosuvastatine/ezetimibe EGIS 20 mg/10 mg capsules, hard	NL/H/3016/002/DC	RVG 113991	EGIS PHARMACEUTICALS PLC	NL
Rosuvastatine/ezetimibe EGIS 40 mg/10 mg capsule, hard	NL/H/3016/003/DC	RVG 113992	EGIS PHARMACEUTICALS PLC	NL

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ROZOR 10 mg/10 mg comprimidos revestidos por película	NL/H/3647/001/DC	5718739	BGP PRODUCTS UNIPESSOAL, LDA.	PT
ROZOR 10 mg/10 mg comprimidos revestidos por película	NL/H/3647/001/DC	5718747	BGP PRODUCTS UNIPESSOAL, LDA.	PT
ROZOR 10 mg/10 mg comprimidos revestidos por película	NL/H/3647/001/DC	5718754	BGP PRODUCTS UNIPESSOAL, LDA.	PT
ROZOR 10 mg/10 mg comprimidos revestidos por película	NL/H/3647/001/DC	5718762	BGP PRODUCTS UNIPESSOAL, LDA.	PT
Rozor 10 mg/10 mg filmdragerade tabletter	NL/H/3647/001/DC	54350	BGP PRODUCTS AB	SE
Twicor 10 mg/10 mg potahované tablety	NL/H/3647/001/DC	31/511/16-C	BGP PRODUCTS CZECH REPUBLIC S.R.O.	CZ
Rozor, 10 mg + 10 mg, tabletki powlekane	NL/H/3647/001	24220	BGP PRODUCTS POLAND SP. Z.O.O.	PL
Twicor 10 mg/10 mg filmomhulde tabletten	NL/H/3647/001	RVG 118789	BGP PRODUCTS B.V.	NL
ROZOR 10 mg/10 mg filmsko obložene tablete	NL/H/3647/001	H/17/02395/001	GSP PROIZVODI D.O.O.	SI
ROZOR 10 mg/10 mg filmsko obložene tablete	NL/H/3647/001	H/17/02395/002	GSP PROIZVODI D.O.O.	SI
ROZOR 10 mg/10 mg filmsko obložene tablete	NL/H/3647/001	H/17/02395/003	GSP PROIZVODI D.O.O.	SI
ROZOR 10 mg/10 mg filmsko obložene tablete	NL/H/3647/001	H/17/02395/004	GSP PROIZVODI D.O.O.	SI