11 April 2024
EMA/170085/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: rosuvastatin/ perindopril /indapamide

Procedure no.: PSUSA/00010752/202308

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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
Roxiper 10 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/001	OGYI-T-23443/01	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/001	OGYI-T-23443/02	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/001	OGYI-T-23443/03	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/001	OGYI-T-23443/04	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/001	OGYI-T-23443/05	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/002	OGYI-T-23443/06	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/002	OGYI-T-23443/07	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/002	OGYI-T-23443/08	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/002	OGYI-T-23443/09	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/4 mg/1,25 mg filmtabletta	HU/H/0484/002	OGYI-T-23443/10	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/003	OGYI-T-23443/11	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/003	OGYI-T-23443/12	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/003	OGYI-T-23443/13	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/003	OGYI-T-23443/14	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/003	OGYI-T-23443/15	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/004	OGYI-T-23443/16	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/004	OGYI-T-23443/17	KRKA, D.D., NOVO MESTO	HU

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Roxiper 20 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/004	OGYI-T-23443/18	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/004	OGYI-T-23443/19	KRKA, D.D., NOVO MESTO	HU
Roxiper 20 mg/8 mg/2,5 mg filmtabletta	HU/H/0484/004	OGYI-T-23443/20	KRKA, D.D., NOVO MESTO	HU
Roxiper 10 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/001	H/18/02491/001	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/001	H/18/02491/002	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/001	H/18/02491/003	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/001	H/18/02491/004	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/001	H/18/02491/005	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/001	H/18/02491/006	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/002	H/18/02491/007	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/002	H/18/02491/008	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/002	H/18/02491/009	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/002	H/18/02491/010	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/002	H/18/02491/011	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/4 mg/1,25 mg filmsko obložene tablete	HU/H/0484/002	H/18/02491/012	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/003	H/18/02491/013	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/003	H/18/02491/014	KRKA, D.D., NOVO MESTO	SI

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Roxiper 10 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/003	H/18/02491/015	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/003	H/18/02491/016	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/003	H/18/02491/017	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/003	H/18/02491/018	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/004	H/18/02491/019	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/004	H/18/02491/020	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/004	H/18/02491/021	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/004	H/18/02491/022	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/004	H/18/02491/023	KRKA, D.D., NOVO MESTO	SI
Roxiper 20 mg/8 mg/2,5 mg filmsko obložene tablete	HU/H/0484/004	H/18/02491/024	KRKA, D.D., NOVO MESTO	SI
Roxiper 10 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/001	LT/1/18/4270/001	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/001	LT/1/18/4270/002	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/001	LT/1/18/4270/003	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/001	LT/1/18/4270/004	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/001	LT/1/18/4270/005	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/001	LT/1/18/4270/006	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/002	LT/1/18/4271/001	KRKA, D.D., NOVO MESTO	LT

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Roxiper 20 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/002	LT/1/18/4271/002	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/002	LT/1/18/4271/003	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/002	LT/1/18/4271/004	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/002	LT/1/18/4271/005	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/4 mg/1,25 mg plėvele dengtos tabletės	HU/H/0484/002	LT/1/18/4271/006	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/003	LT/1/18/4272/001	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/003	LT/1/18/4272/002	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/003	LT/1/18/4272/003	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/003	LT/1/18/4272/004	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/003	LT/1/18/4272/005	KRKA, D.D., NOVO MESTO	LT
Roxiper 10 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/003	LT/1/18/4272/006	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/004	LT/1/18/4273/001	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/004	LT/1/18/4273/002	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/004	LT/1/18/4273/003	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/004	LT/1/18/4273/004	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/004	LT/1/18/4273/005	KRKA, D.D., NOVO MESTO	LT
Roxiper 20 mg/8 mg/2,5 mg plėvele dengtos tabletės	HU/H/0484/004	LT/1/18/4273/006	KRKA, D.D., NOVO MESTO	LT

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Roxiper 10 mg/4 mg/1,25 mg filmom obalené tablety	HU/H/0484/001	58/0267/18-S	KRKA, D.D., NOVO MESTO	SK
Roxiper 10 mg/8 mg/2,5 mg filmom obalené tablety	HU/H/0484/003	58/0268/18-S	KRKA, D.D., NOVO MESTO	SK
Roxiper 20 mg/4 mg/1,25 mg filmom obalené tablety	HU/H/0484/002	58/0269/18-S	KRKA, D.D., NOVO MESTO	SK
Roxiper 20 mg/8 mg/2,5 mg filmom obalené tablety	HU/H/0484/004	58/0270/18-S	KRKA, D.D., NOVO MESTO	SK
Роксипер 10 mg/4 mg/1,25 mg филмирани таблетки	HU/H/0484/001	20180255	KRKA, D.D., NOVO MESTO	BG
Роксипер 20 mg/4 mg/1,25 mg филмирани таблетки	HU/H/0484/002	20180256	KRKA, D.D., NOVO MESTO	BG
Роксипер 10 mg/8 mg/2,5 mg филмирани таблетки	HU/H/0484/003	20180257	KRKA, D.D., NOVO MESTO	BG
Роксипер 20 mg/8 mg/2,5 mg филмирани таблетки	HU/H/0484/004	20180258	KRKA, D.D., NOVO MESTO	BG
Roxiper 10 mg + 4 mg + 1,25 mg comprimidos revestidos por película	HU/H/0484/001	5756812	KRKA, D.D., NOVO MESTO	PT
Roxiper 10 mg + 8 mg + 2,5 mg comprimidos revestidos por película	HU/H/0484/003	5756820	KRKA, D.D., NOVO MESTO	PT
Roxiper 20 mg + 4 mg + 1,25 mg comprimidos revestidos por película	HU/H/0484/002	5756838	KRKA, D.D., NOVO MESTO	PT
Roxiper 20 mg + 8 mg + 2,5 mg comprimidos revestidos por película	HU/H/0484/004	5756846	KRKA, D.D., NOVO MESTO	PT
Roxiper 10 mg/4 mg/1,25 mg õhukese polümeerikattega tabletid	HU/H/0484/001	971418	KRKA, D.D., NOVO MESTO	EE
Roxiper 10 mg/8 mg/2,5 mg õhukese polümeerikattega tabletid	HU/H/0484/003	971518	KRKA, D.D., NOVO MESTO	EE

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Roxiper 20 mg/4 mg/1,25 mg õhukese polümeerikattega tabletid	HU/H/0484/002	971618	KRKA, D.D., NOVO MESTO	EE
Roxiper 20 mg/8 mg/2,5 mg õhukese polümeerikattega tabletid	HU/H/0484/004	971718	KRKA, D.D., NOVO MESTO	EE
Triemma 10 mg/4 mg/1,25 mg apvalkotās tabletes	HU/H/0484/001	18-0133	KRKA, D.D., NOVO MESTO	LV
Triemma 20 mg/4 mg/1,25 mg apvalkotās tabletes	HU/H/0484/002	18-0134	KRKA, D.D., NOVO MESTO	LV
Triemma 10 mg/8 mg/2,5 mg apvalkotās tabletes	HU/H/0484/003	18-0135	KRKA, D.D., NOVO MESTO	LV
Triemma 20 mg/8 mg/2,5 mg apvalkotās tabletes	HU/H/0484/004	18-0136	KRKA, D.D., NOVO MESTO	LV
Roxiper 10 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/001	11165/2018/01	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/001	11165/2018/02	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/001	11165/2018/03	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/001	11165/2018/04	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/001	11165/2018/05	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/001	11165/2018/06	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/002	11166/2018/01	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/002	11166/2018/02	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/002	11166/2018/03	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/002	11166/2018/04	KRKA, D.D., NOVO MESTO	RO

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Roxiper 20 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/002	11166/2018/05	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/4 mg/1,25 mg comprimate filmate	HU/H/0484/002	11166/2018/06	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/003	11167/2018/01	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/003	11167/2018/02	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/003	11167/2018/03	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/003	11167/2018/04	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/003	11167/2018/05	KRKA, D.D., NOVO MESTO	RO
Roxiper 10 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/003	11167/2018/06	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/004	11168/2018/01	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/004	11168/2018/02	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/004	11168/2018/03	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/004	11168/2018/04	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/004	11168/2018/05	KRKA, D.D., NOVO MESTO	RO
Roxiper 20 mg/8 mg/2,5 mg comprimate filmate	HU/H/0484/004	11168/2018/06	KRKA, D.D., NOVO MESTO	RO
Roxiper, 10 mg + 4 mg + 1,25 mg, tabletki powlekane	HU/H/0484/001	25063	KRKA, D.D., NOVO MESTO	PL
Roxiper, 20 mg + 4 mg + 1,25 mg, tabletki powlekane	HU/H/0484/002	25064	KRKA, D.D., NOVO MESTO	PL
Roxiper, 10 mg + 8 mg + 2,5 mg, tabletki powlekane	HU/H/0484/003	25065	KRKA, D.D., NOVO MESTO	PL

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Roxiper, 20 mg + 8 mg + 2,5 mg, tabletki powlekane	HU/H/0484/004	25066	KRKA, D.D., NOVO MESTO	PL
Roxiper 10 mg/4 mg/1,25 mg kalvopäällysteiset tabletit	HU/H/0484/001	34683	KRKA, D.D., NOVO MESTO	FI
Roxiper 20 mg/4 mg/1,25 mg kalvopäällysteiset tabletit	HU/H/0484/002	34684	KRKA, D.D., NOVO MESTO	FI
Roxiper 10 mg/8 mg/2,5 mg kalvopäällysteiset tabletit	HU/H/0484/003	34685	KRKA, D.D., NOVO MESTO	FI
Roxiper 20 mg/8 mg/2,5 mg kalvopäällysteiset tabletit	HU/H/0484/004	34686	KRKA, D.D., NOVO MESTO	FI
Roxiper 20 mg/4 mg/1,25 mg filmom obložene tablete	not available	HR-H-519761227	KRKA-FARMA D.O.O.	HR
Roxiper 20 mg/8 mg/2,5 mg filmom obložene tablete	not available	HR-H-621028210	KRKA-FARMA D.O.O.	HR
Roxiper 10 mg/4 mg/1,25 mg filmom obložene tablete	not available	HR-H-623362895	KRKA-FARMA D.O.O.	HR
Roxiper 10 mg/8 mg/2,5 mg filmom obložene tablete	not available	HR-H-638321830	KRKA-FARMA D.O.O.	HR