



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 September 2021
EMA/583331/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: propafenone

Procedure no.: PSUSA/00002550/202101

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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
Arythmol 150 mg Tablets	not available	PL 46302/0001	MYLAN PRODUCTS LIMITED	XI
Arythmol 300 mg Tablets	not available	PL 46302/0002	MYLAN PRODUCTS LIMITED	XI
RYTHMOL 300 mg, comprimé pelliculé sécable	not available	34009 326 571 0 0	MYLAN MEDICAL SAS	FR
RYTHMOL 300 mg, comprimé pelliculé sécable	not available	34009 326 572 7 8	MYLAN MEDICAL SAS	FR
Rytmonorm® 150 mg Filmtablette	not available	343.00.00	MYLAN HEALTHCARE GMBH	DE
Rytmonorm 150 mg apvalkotās tabletes	not available	95-0017	MYLAN HEALTHCARE SIA	LV
Rytmonorm 150 mg Comprese rivestite	not available	024862070	TEVA ITALIA S.R.L.	IT
Rytmonorm 150 mg Comprese rivestite	not available	024862017	TEVA ITALIA S.R.L.	IT
Rytmonorm 150 mg comprimate filmate	not available	7093/2014/01	MYLAN HEALTHCARE GMBH	RO

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
RYTMONORM 150 mg comprimés pelliculés	not available	2000066217	TEVA B.V	LU
RYTMONORM 150 mg comprimés pelliculés.	not available	BE129166	TEVA B.V	BE
Rytmonorm 150 mg comprimido revestido	not available	8543124	BGP PRODUCTS UNIPESOAL, LDA.	PT
Rytmonorm 150 mg comprimido revestido	not available	5551387	BGP PRODUCTS UNIPESOAL, LDA.	PT
Rytmonorm 150 mg comprimidos recubiertos	not available	55538	TEVA B.V	ES
Rytmonorm 150 mg filmom obložene tablete	not available	HR-H-869129052	MYLAN HRVATSKA D.O.O.	HR
Rytmonorm 150 mg filmsko obložene tablete	not available	H/94/01385/001	MYLAN IRE HEALTHCARE LIMITED	SI
Rytmonorm 150 mg filmtabletta	not available	OGYI-T-2006/02	MYLAN EPD KFT.	HU
Rytmonorm 150 mg filmtabletta	not available	OGYI-T-2006/02	MYLAN EPD KFT.	HU

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
Rytmonorm 150 mg filmtabletta	not available	OGYI-T-2006/02	MYLAN EPD KFT.	HU
Rytmonorm 150 mg plėvele dengtos tabletės	not available	LT/1/94/1020/001	MYLAN HEALTHCARE SIA	LT
Rytmonorm 150 mg potahované tablety	not available	13/133/85-B/C	MYLAN IRE HEALTHCARE LIMITED	CZ
Rytmonorm 150 mg filmom obalené tablety	not available	13/0133/85-C/S	MYLAN IRE HEALTHCARE LIMITED	SK
Rytmonorm 150 mg, filmdragerade tabletter	not available	11309	BGP PRODUCTS AB	SE
RYTMONORM 150 mg, filmomhulde tabletten.	not available	BE129166	TEVA B.V	BE
Rytmonorm 150 mg, Filmtabletten	not available	BE129166	TEVA B.V	BE
Rytmonorm 150 mg, omhulde tabletten	not available	RVG 12448	MYLAN HEALTHCARE B.V.	NL
Rytmonorm 150, 150 mg, tabletki powlekane	not available	R/1008	MYLAN HEALTHCARE SP. Z.O.O.	PL

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
RYTMONORM 225 mg comprimés pelliculés.	not available	BE167273	TEVA B.V	BE
RYTMONORM 225 mg, filmomhulde tabletten	not available	BE167273	TEVA B.V	BE
Rytmonorm 225 mg, Filmtabletten	not available	BE167273	TEVA B.V	BE
Rytmonorm 3,5 mg/ml oldatos injekció	not available	OGYI-T-2008/01	MYLAN EPD KFT.	HU
Rytmonorm 3,5 mg/ml oldatos injekció	not available	OGYI-T-2008/01	MYLAN EPD KFT.	HU
Rytmonorm 3,5 mg/ml oldatos injekció	not available	OGYI-T-2008/01	MYLAN EPD KFT.	HU
Rytmonorm 3,5 mg/ml solución inyectable	not available	58275	TEVA B.V	ES
Rytmonorm 3,5 mg/ml solución inyectable	not available	58275	TEVA B.V	ES
Rytmonorm 300 mg apvalkotās tabletes	not available	00-0739	MYLAN HEALTHCARE SIA	LV

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
Rytmonorm 300 mg Comprese rivestite	not available	024862082	TEVA ITALIA S.R.L.	IT
Rytmonorm 300 mg Comprese rivestite	not available	024862029	TEVA ITALIA S.R.L.	IT
RYTMONORM 300 mg comprimés pelliculés	not available	1998104734	TEVA B.V	LU
RYTMONORM 300 mg comprimés pelliculés.	not available	BE129157	TEVA B.V	BE
Rytmonorm 300 mg comprimido revestido	not available	5551486	BGP PRODUCTS UNIPESOAL, LDA.	PT
Rytmonorm 300 mg comprimidos recubiertos	not available	55541	TEVA B.V	ES
Rytmonorm 300 mg filmom obložene tablete	not available	HR-H-361093310	MYLAN HRVATSKA D.O.O.	HR
Rytmonorm 300 mg filmsko obložene tablete	not available	H/94/01385/002	MYLAN IRE HEALTHCARE LIMITED	SI
Rytmonorm 300 mg filmtabletta	not available	OGYI-T-2007/02	MYLAN EPD KFT.	HU

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
Rytmonorm 300 mg filmtabletta	not available	OGYI-T-2007/01	MYLAN EPD KFT.	HU
Rytmonorm 300 mg filmtabletta	not available	OGYI-T-2007/02	MYLAN EPD KFT.	HU
Rytmonorm 300 mg filmtabletta	not available	OGYI-T-2007/01	MYLAN EPD KFT.	HU
Rytmonorm 300 mg filmtabletta	not available	OGYI-T-2007/01	MYLAN EPD KFT.	HU
Rytmonorm 300 mg plėvele dengtos tabletės	not available	LT/1/94/1020/002	MYLAN HEALTHCARE SIA	LT
Rytmonorm 300 mg potahované tablety	not available	13/133/85-C/C	MYLAN IRE HEALTHCARE LIMITED	CZ
Rytmonorm 300 mg filmom obalené tablety	not available	13/0347/17-S	MYLAN IRE HEALTHCARE LIMITED	SK
Rytmonorm 300 mg, filmdragerade tabletter	not available	11310	BGP PRODUCTS AB	SE
RYTMONORM 300 mg, filmomhulde tabletten.	not available	BE129157	TEVA B.V	BE

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
Rytmonorm 300 mg, Filmtabletten	not available	BE129157	TEVA B.V	BE
Rytmonorm 300 mg, omhulde tabletten	not available	RVG 12449	MYLAN HEALTHCARE B.V.	NL
Rytmonorm 300, 300 mg, tabletki powlekane	not available	R/1009	MYLAN HEALTHCARE SP. Z.O.O.	PL
Rytmonorm 325 mg Capsule rigide a rilascio prolungato	not available	024862094	TEVA ITALIA S.R.L.	IT
Rytmonorm 425 mg Capsule rigide a rilascio prolungato	not available	024862106	TEVA ITALIA S.R.L.	IT
Rytmonorm 70 mg/20 ml otopina za injekciju/infuziju	not available	HR-H-271347714	MYLAN HRVATSKA D.O.O.	HR
Rytmonorm 70 mg/20 ml soluție injectabilă	not available	7094/2014/01	MYLAN HEALTHCARE GMBH	RO
Rytmonorm 70 mg/20 ml Soluzione iniettabile per uso endovenoso	not available	024862031	TEVA ITALIA S.R.L.	IT
Rytmonorm injekcie 70 mg/20 ml injekčný roztok	not available	13/0134/85-CS	MYLAN IRE HEALTHCARE LIMITED	SK

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
Rytmonorm SR 225 mg Tvrde kapsuly s predizenyim uvolnovanim	DE/H/3854/001	13/0308/05-S	TS PHARMA S.R.O.	SK
Rytmonorm SR 325 mg Tvrde kapsuly s predizenyim uvolnovanim	DE/H/3854/002	13/0309/05-S	TS PHARMA S.R.O.	SK
Rytmonorm SR 425 mg Tvrde kapsuly s predizenyim uvolnovanim	DE/H/3854/003	13/0310/05-S	TS PHARMA S.R.O.	SK
Rytmonorm, 150 mg dhukese polumeerikattega tabletid	not available	220998	MYLAN HEALTHCARE SIA	EE
Rytmonorm, 3,5 mg/ml, roztwor do wstrzykiwan	not available	R/1251	MYLAN HEALTHCARE SP. Z.O.O.	PL
Rytmonorm, 300 mg dhukese polumeerikattega tabletid	not available	221098	MYLAN HEALTHCARE SIA	EE
Rytmonorm, filmovertrukne tableter	not available	11071	MYLAN DENMARK APS	DK
Rytmonorm, filmovertrukne tableter	not available	11070	MYLAN DENMARK APS	DK
Rytmonorm® 300 mg Filmtablette	not available	343.01.00	MYLAN HEALTHCARE GMBH	DE

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
Rytmonorm® SR 225 mg Hartkapseln, retardiert	DE/H/3854/001	61919.00.00	MYLAN HEALTHCARE GMBH	DE
Rytmonorm® SR 325 mg Hartkapseln, retardiert	DE/H/3854/002	61920.00.00	MYLAN HEALTHCARE GMBH	DE
Rytmonorm® SR 425 mg Hartkapseln, retardiert	DE/H/3854/003	61921.00.00	MYLAN HEALTHCARE GMBH	DE
Rytmonorm®, 70 mg/20 ml, Injektionslösung	not available	343.00.01	MYLAN HEALTHCARE GMBH	DE
Rytmonorma - Ampullen	not available	17435	MYLAN ÖSTERREICH GMBH	AT
Rytmonorma - Ampullen	not available	17435	MYLAN ÖSTERREICH GMBH	AT
Rytmonorma 150 mg - Filmdoublets	not available	16590	MYLAN ÖSTERREICH GMBH	AT
Rytmonorma 150 mg - Filmdoublets	not available	16590	MYLAN ÖSTERREICH GMBH	AT
Rytmonorma 300 mg - Filmdoublets	not available	16481	MYLAN ÖSTERREICH GMBH	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
Rytmonorma 300 mg - Filmtabletten	not available	16481	MYLAN ÖSTERREICH GMBH	AT
Ρυθμονόρμ®	not available	07291	MYLAN IRE HEALTHCARE LIMITED	CY
Ρυθμονόρμ®	not available	8571	BGP PRODUCTS S.LTD	GR
Ρυθμονόρμ®	not available	8571	BGP PRODUCTS S.LTD	GR
ΡΥΘΜΟΝΟΡΜ® SR 225 mg καψάκιο παρατεταμένης αποδέσμευσης, σκληρό	DE/H/3854/001	49839/11-07-2011	BGP PRODUCTS S.LTD	GR
ΡΥΘΜΟΝΟΡΜ® SR 325 mg καψάκιο παρατεταμένης αποδέσμευσης, σκληρό	DE/H/3854/002	49840/11-07-2011	BGP PRODUCTS S.LTD	GR
ΡΥΘΜΟΝΟΡΜ® SR 425 mg καψάκιο παρατεταμένης αποδέσμευσης, σκληρό	DE/H/3854/003	49837/11-07-2011	BGP PRODUCTS S.LTD	GR
Ритмонорм 150 mg филмирани таблетки	not available	20020603	MYLAN EOOD	BG
Ритмонорм 300 mg филмирани таблетки	not available	20020602	MYLAN EOOD	BG