



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2024
EMA/470269/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: rupatadine

Procedure no.: PSUSA/00002673/202312

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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
Rupafin 1 mg/ml Lösung zum Einnehmen	ES/H/0105/002	1-31463	NOUCOR HEALTH, S.A.	AT
Rupafin 10 mg Tabletten	ES/H/0105/001	1-27273	NOUCOR HEALTH, S.A.	AT
Rupatall 1 mg/ml drank	ES/H/0105/002	BE418153	NOUCOR HEALTH, S.A.	BE
Rupatall 1 mg/ml Lösung zum Einnehmen	ES/H/0105/002	BE418153	NOUCOR HEALTH, S.A.	BE
Rupatall 1 mg/ml solution buvable	ES/H/0105/002	BE418153	NOUCOR HEALTH, S.A.	BE
Rupatall 10 mg comprimés	ES/H/0105/001	BE272045	NOUCOR HEALTH, S.A.	BE
Рупафин 1 mg/ml перорален разтвор	ES/H/0105/002	20130384	NOUCOR HEALTH, S.A.	BG
Рупафин 10 mg таблетки	ES/H/0105/001	20130385	NOUCOR HEALTH, S.A.	BG
Rupafin 1 mg/ml πόσιμο διάλυμα	ES/H/0105/002	21571	NOUCOR HEALTH, S.A.	CY

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
Rupafin 10 mg Δισκία	ES/H/0105/001	20316	NOUCOR HEALTH, S.A.	CY
Tamalis 1 mg/ml perorální roztok	ES/H/0105/002	24/592/12-C	NOUCOR HEALTH, S.A.	CZ
TAMALIS 10 mg tablety	ES/H/0105/001	24/273/07-C	NOUCOR HEALTH, S.A.	CZ
Rupafin 1 mg/ml Lösung zum Einnehmen	ES/H/0105/002	84256.00.00	NOUCOR HEALTH, S.A.	DE
Urtimed 1 mg/ml Lösung zum Einnehmen	ES/H/0134/002	84257.00.00	BIOHORM,S.L.	DE
Urtimed® 10 mg Tabletten	ES/H/0134/001	68012.00.00	BIOHORM,S.L.	DE
Rupafin, oral opløsning	ES/H/0105/001	52335	NOUCOR HEALTH, S.A.	DK
Rupafin, tabletter	ES/H/0105/001	52334	NOUCOR HEALTH, S.A.	DK
Rupafin, 1 mg/ml suukaudne lahus	ES/H/0105/002	780212	NOUCOR HEALTH, S.A.	EE

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
Rupafin, 10 mg tabletid	ES/H/0105/001	549607	NOUCOR HEALTH, S.A.	EE
Alergoliber 1 mg/ml Solución oral	ES/H/0134/002	75694	BIOHORM,S.L.	ES
Alergoliber 10 mg Comprimidos	ES/H/0134/001	65350	BIOHORM,S.L.	ES
Rescetina 10 mg comprimidos	not available	82384	URQUIMA S.A.	ES
Rinialer 1 mg/ml Solución oral	not available	75990	NOUCOR HEALTH, S.A.	ES
Rinialer 10 mg Comprimidos	not available	65367	NOUCOR HEALTH, S.A.	ES
Rupafin 1 mg/ml solución oral	ES/H/0105/002	75666	LABORATORIOS ERN, S.A.	ES
Rupafin 10 mg comprimidos	ES/H/0105/001	64.053	LABORATORIOS ERN, S.A.	ES
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 382 884 0 7	NOUCOR HEALTH, S.A.	FR

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
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 382 885 7 5	NOUCOR HEALTH, S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 384 158 5 8	NOUCOR HEALTH, S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 384 159 1 9	NOUCOR HEALTH, S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 384 161 6 9	NOUCOR HEALTH, S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 384 162 2 0	NOUCOR HEALTH, S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 572 215 2 2	NOUCOR HEALTH, S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	34009 572 216 9 0	NOUCOR HEALTH, S.A.	FR
Rupafin 1 mg/ml πόσιμο διάλυμα	ES/H/0105/002	2536102	GALENICA SA	GR
Rupafin 10 mg Δισκία	ES/H/0105/001	2536101	GALENICA SA	GR

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
Rupafin 1 mg/ml oralna otopina	ES/H/0105/001	HR-H-145923586	NOUCOR HEALTH, S.A.	HR
Rupafin 10 mg tablete	ES/H/0105/001	HR-H-009571007	NOUCOR HEALTH, S.A.	HR
Tamalis 1 mg/ml belsőleges oldat	ES/H/0105/002	OGYI-T-20788/05	NOUCOR HEALTH, S.A.	HU
Tamalis 10 mg tabletta	ES/H/0105/001	OGYI-T-20788/01	NOUCOR HEALTH, S.A.	HU
Tamalis 10 mg tabletta	ES/H/0105/001	OGYI-T-20788/02	NOUCOR HEALTH, S.A.	HU
Tamalis 10 mg tabletta	ES/H/0105/001	OGYI-T-20788/03	NOUCOR HEALTH, S.A.	HU
Tamalis 10 mg tabletta	ES/H/0105/001	OGYI-T-20788/04	NOUCOR HEALTH, S.A.	HU
Rupafin 1 mg/ml Oral Solution	ES/H/0105/002	PA1129/001/002	NOUCOR HEALTH, S.A.	IE
Rupafin 10 mg Tablets	ES/H/0105/001	PA 1129/001/001	NOUCOR HEALTH, S.A.	IE

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
Rupafin 1 mg/ml mixtúra, lausn	ES/H/0105/002	IS/1/13/066/01	NOUCOR HEALTH, S.A.	IS
Rupafin 10 mg töflur	ES/H/0105/001	IS/1/13/066/02	NOUCOR HEALTH, S.A.	IS
Pafinur 1 mg/ml soluzione orale	ES/H/0134/002	037888094	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888029	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888031	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888043	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888056	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888068	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888070	BIOHORM,S.L.	IT

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
Pafinur 10 mg compresse	ES/H/0134/001	037888082	BIOHORM,S.L.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888017	BIOHORM,S.L.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880010	NOUCOR HEALTH, S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880022	NOUCOR HEALTH, S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880034	NOUCOR HEALTH, S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880046	NOUCOR HEALTH, S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880059	NOUCOR HEALTH, S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880061	NOUCOR HEALTH, S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880073	NOUCOR HEALTH, S.A.	IT

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
Rupafin 10 mg compresse	ES/H/0105/001	037880085	NOUCOR HEALTH, S.A.	IT
Rupafin 1mg/ml Soluzione orale	ES/H/0105/002	037880097	NOUCOR HEALTH, S.A.	IT
Rupafin 1 mg/ml geriamasis tirpala	ES/H/0105/002	LT/1/08/1006/009	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletės	ES/H/0105/001	LT/1/08/1006/001	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletės	ES/H/0105/001	LT/1/08/1006/002	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletės	ES/H/0105/001	LT/1/08/1006/003	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletės	ES/H/0105/001	LT/1/08/1006/004	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletės	ES/H/0105/001	LT/1/08/1006/005	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletės	ES/H/0105/001	LT/1/08/1006/006	NOUCOR HEALTH, S.A.	LT

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
Rupafin 10 mg tabletēs	ES/H/0105/001	LT/1/08/1006/007	NOUCOR HEALTH, S.A.	LT
Rupafin 10 mg tabletēs	ES/H/0105/001	LT/1/08/1006/008	NOUCOR HEALTH, S.A.	LT
Rupatall 1 mg/ml solution buvable	ES/H/0105/002	2012090072	NOUCOR HEALTH, S.A.	LU
RUPATALL 10 mg comprimés	ES/H/0105/001	2011071198	NOUCOR HEALTH, S.A.	LU
Rupafin 10 mg tabletēs	ES/H/0105/001	07-0302	NOUCOR HEALTH, S.A.	LV
Rupafin 1mg/ml šķīdums iekšķīgai lietošanai	ES/H/0105/002	12-0080	NOUCOR HEALTH, S.A.	LV
Rinialer 1 mg/ml Oral Solution	ES/H/0105/002	MA004/00801	BIAL - PORTELA & C ^a , SA	MT
Rinialer 10 mg Tablets	ES/H/0105/001	MA004/00601	BIAL - PORTELA & C ^a , SA	MT
Rupafin 1 mg/ml drank	ES/H/0105/002	RVG 108903	NOUCOR HEALTH, S.A.	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
Rupafin 10 mg tabletten	ES/H/0105/001	RVG 34425	NOUCOR HEALTH, S.A.	NL
Rupafin 1 mg/ml mikstur, oppløsning.	ES/H/0105/002	13-9499	NOUCOR HEALTH, S.A.	NO
Rupafin 10 mg tabletter	ES/H/0105/001	13-9498	NOUCOR HEALTH, S.A.	NO
Rupafin 10 mg, tabletki	ES/H/0105/001	14244	NOUCOR HEALTH, S.A.	PL
Rupafin, 1 mg/ml, roztwór doustny	ES/H/0105/002	20340	NOUCOR HEALTH, S.A.	PL
Rinialer 1 mg/ml solução oral	ES/H/105/002	5453253	BIAL - PORTELA & C ^a , SA	PT
RINIALER 10 mg comprimidos	ES/H/105/001	3843588	BIAL - PORTELA & C ^a , SA	PT
RINIALER 10 mg comprimidos	ES/H/105/001	3843687	BIAL - PORTELA & C ^a , SA	PT
Tamalis 1 mg/ml soluție orală	ES/H/0105/001	9661/2017/01	NOUCOR HEALTH, S.A.	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
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/01	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/02	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/03	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/04	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/05	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/06	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/07	NOUCOR HEALTH, S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	9660/2017/08	NOUCOR HEALTH, S.A.	RO
Pafinur 1 mg/ml oral lösning	ES/H/0105/002	49270	NOUCOR HEALTH, S.A.	SE

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
Pafinur 10 mg tabletter	ES/H/0105/001	49269	NOUCOR HEALTH, S.A.	SE
Rupafin 1 mg/ml peroralna raztopina	ES/H/0105/002	H/08/01382/009	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/001	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/002	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/003	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/004	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/005	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/006	NOUCOR HEALTH, S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/007	NOUCOR HEALTH, S.A.	SI

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
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/008	NOUCOR HEALTH, S.A.	SI
Rupafin 1 mg/ml perorálny roztok	ES/H/0105/002	24/0124/12-S	NOUCOR HEALTH, S.A.	SK
Rupafin 10 mg tablety	ES/H/0105/001	24/0148/07-S	NOUCOR HEALTH, S.A.	SK
Rupatadine 1 mg/ml oral solution	ES/H/0105/002	PL35533/0186	ASPIRE PHARMA LIMITED	XI
Rupatadine 10 mg Tablets	ES/H/0105/001	PL 35533/0185	ASPIRE PHARMA LIMITED	XI