



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

1 September 2017  
EMA/579949/2017  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: rupatadine

Procedure no.: PSUSA/00002673/201612



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Alergoliber 1 mg/ml Solución oral	ES/H/0134/002	75694	BIOHORM, S.A.	ES
Alergoliber 10 mg Comprimidos	ES/H/0134/001	65350	BIOHORM, S.A.	ES
Pafinur 1 mg/ml oraaliliuos	ES/H/0105/002	31442	J. URIACH & CÍA., S.A.	FI
Pafinur 1 mg/ml oral lösning	ES/H/0105/002	49270	J. URIACH & CÍA., S.A.	SE
Pafinur 1 mg/ml soluzione orale	ES/H/0134/002	037888094	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888029	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888031	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888043	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888056	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888068	BIOHORM, S.A.	IT

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Pafinur 10 mg compresse	ES/H/0134/001	037888070	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888082	BIOHORM, S.A.	IT
Pafinur 10 mg compresse	ES/H/0134/001	037888017	BIOHORM, S.A.	IT
Pafinur 10 mg tabletit	ES/H/0105/001	31441	J. URIACH & CÍA., S.A.	FI
Pafinur 10 mg tableter	ES/H/0105/001	49269	J. URIACH & CÍA., S.A.	SE
Rinialer 1 mg/ml Oral Solution	ES/H/0105/002	MA004/00801	BIAL - PORTELA & C <sup>a</sup> , SA	MT
Rinialer 1 mg/ml solução oral	ES/H/0105/002	5453253	BIALFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Rinialer 1 mg/ml Solución oral	not available	75990	J. URIACH & CÍA., S.A.	ES
Rinialer 10 mg Comprimidos	not available	65367	J. URIACH & CÍA., S.A.	ES

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RINIALER 10 mg comprimidos	ES/H/0105/001	3843687	BIALFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
RINIALER 10 mg comprimidos	ES/H/0105/001	3843588	BIALFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Rinialer 10 mg Tablets	ES/H/0105/001	MA004/00601	BIAL - PORTELA & C <sup>a</sup> , SA	MT
Rupafin 1 mg / ml Lösung zum Einnehmen	ES/H/0105/002	1-31463	J. URIACH & CÍA., S.A.	AT
Rupafin 1 mg/ml drank	ES/H/0105/002	RVG 108903	J. URIACH & CÍA., S.A.	NL
Rupafin 1 mg/ml geriamasis tirpalas	ES/H/0105/002	LT/1/08/1006/009	J. URIACH & CÍA., S.A.	LT
Rupafin 1 mg/ml Lösung zum Einnehmen	ES/H/0105/002	84256.00.00	J. URIACH & CÍA., S.A.	DE
Rupafin 1 mg/ml mikstur, oppløsning.	ES/H/0105/001-002/E/003	139499	J. URIACH & CÍA., S.A.	NO
Rupafin 1 mg/ml mixtúra, lausn	ES/H/0105/001-002/E/003	IS/1/13/066/01	J. URIACH & CÍA., S.A.	IS

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 Oral Solution	ES/H/0105/002	PA 1129/001/002	J. URIACH & CÍA., S.A.	IE
Rupafin 1 mg/ml Oral Solution	ES/H/0105/002	PL 11906/0009	J. URIACH & CÍA., S.A.	UK
Rupafin 1 mg/ml oralna otopina	ES/H/0105/001	UP/I-530-09/13-01/28	J. URIACH & CÍA., S.A.	HR
Rupafin 1 mg/ml peroralna raztopina	ES/H/0105/002/DC	H/08/01382/009	J. URIACH & CÍA., S.A.	SI
Rupafin 1 mg/ml perorálny roztok	ES/H/0105/002	24/0124/12-S	J. URIACH & CÍA., S.A.	SK
Rupafin 1 mg/ml πόσιμο διάλυμα	ES/H/0105/002	21571	J. URIACH & CÍA., S.A.	CY
Rupafin 1 mg/ml, oral opløsning	ES/H/0105/001	28756	J. URIACH & CÍA., S.A.	DK
Rupafin 10 mg compresse	ES/H/0105/001	037880010	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880022	J. URIACH & CÍA., S.A.	IT

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Rupafin 10 mg compresse	ES/H/0105/001	037880034	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880046	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880059	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880061	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880073	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg compresse	ES/H/0105/001	037880085	J. URIACH & CÍA., S.A.	IT
Rupafin 10 mg tablete	ES/H/0105/001	UP/I-530-09/13-01/29	J. URIACH & CÍA., S.A.	HR
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/001	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/002	J. URIACH & CÍA., S.A.	SI

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Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/003	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/004	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/005	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/006	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/007	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tablete	ES/H/0105/001	H/08/01382/008	J. URIACH & CÍA., S.A.	SI
Rupafin 10 mg tabletēs	ES/H/0105/001	07-0302	J. URIACH & CÍA., S.A.	LV
Rupafin 10 mg tabletēs	ES/H/0105/001	LT/1/08/1006/001	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg tabletēs	ES/H/0105/001	LT/1/08/1006/002	J. URIACH & CÍA., S.A.	LT

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Rupafin 10 mg tabletès	ES/H/0105/001	LT/1/08/1006/003	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg tabletès	ES/H/0105/001	LT/1/08/1006/004	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg tabletès	ES/H/0105/001	LT/1/08/1006/005	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg tabletès	ES/H/0105/001	LT/1/08/1006/006	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg tabletès	ES/H/0105/001	LT/1/08/1006/007	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg tabletès	ES/H/0105/001	LT/1/08/1006/008	J. URIACH & CÍA., S.A.	LT
Rupafin 10 mg Tablets	ES/H/0105/001	PA 1129/1/1	J. URIACH & CÍA., S.A.	IE
Rupafin 10 mg Tablets	ES/H/0105/001	PL11906/0007	J. URIACH & CÍA., S.A.	UK
Rupafin 10 mg Tabletten	ES/H/0105/001	1-27273	J. URIACH & CÍA., S.A.	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
Rupafin 10 mg Tabletten	ES/H/0105/001	68011.00.00	J. URIACH & CÍA., S.A.	DE
Rupafin 10 mg tabletten.	ES/H/0105/001	RVG 34425	J. URIACH & CÍA., S.A.	NL
Rupafin 10 mg tabletter	ES/H/0105/001-002/E/003	13/9498	J. URIACH & CÍA., S.A.	NO
Rupafin 10 mg tablety	ES/H/0105/001	24/0148/07-S	J. URIACH & CÍA., S.A.	SK
Rupafin 10 mg töflur	ES/H/0105/001-002/E/003	IS/1/13/066/02	J. URIACH & CÍA., S.A.	IS
Rupafin 10 mg Δισκία	ES/H/0105/001	20316	J. URIACH & CÍA., S.A.	CY
Rupafin 10 mg Δισκία	ES/H/0105/001	37818/29-05-2012	OLVOS SCIENCE S.A.	GR
Rupafin 10 mg, tabletki	ES/H/0105/001	14244	J. URIACH & CÍA., S.A.	PL
Rupafin 10 mg, tabletter	ES/H/0105/001	52334	J. URIACH & CÍA., S.A.	DK

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 1mg/ml šķīdums iekšējīgai lietošanai	ES/H/0105/002	12-0080	J. URIACH & CÍA., S.A.	LV
Rupafin 1mg/ml Soluzione orale	ES/H/0105/002	037880097	J. URIACH & CÍA., S.A.	IT
Rupafin 1mg/ml πόσιμο διάλυμα	ES/H/0105/002	64809/26-8-2013	OLVOS SCIENCE S.A.	GR
Rupafin, 1 mg/ml suukaudne lahus	ES/H/0105/002	780212	J. URIACH & CÍA., S.A.	EE
Rupafin, 1 mg/ml, roztwór doustny	ES/H/0105/002	20340	J. URIACH & CÍA., S.A.	PL
Rupafin, 10 mg tabletid	ES/H/0105/001	549607	J. URIACH & CÍA., S.A.	EE
Rupatall 1 mg/ml Lösung zum Einnehmen	ES/H/0105/002	BE418153	J. URIACH & CÍA., S.A.	BE
Rupatall 1 mg/ml solution buvable	ES/H/0105/002	BE418153	J. URIACH & CÍA., S.A.	BE
Rupatall 1 mg/ml solution buvable	ES/H/0105/002	2012090072	J. URIACH & CÍA., S.A.	LU

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RUPATALL 10 mg comprimés	ES/H/0105/001	BE272045	J. URIACH & CÍA., S.A.	BE
RUPATALL 10 mg comprimés	ES/H/0105/001	1528/11071198	J. URIACH & CÍA., S.A.	LU
Tamalis 1 mg/ml belsőleges oldat	ES/H/0105/002	OGYI-T-20788/05	J. URIACH & CÍA., S.A.	HU
Tamalis 1 mg/ml perorální roztok	ES/H/0105/002	24/592/12-C	J. URIACH & CÍA., S.A.	CZ
Tamalis 1 mg/ml soluție orală	ES/H/0105/001	6000/2013/01	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001-002/E/003	5999/2013/01	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	5999/2013/02	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	5999/2013/03	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimate	ES/H/0105/001	5999/2013/04	J. URIACH & CÍA., S.A.	RO

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Tamalis 10 mg comprimato	ES/H/0105/001	5999/2013/05	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimato	ES/H/0105/001	5999/2013/06	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimato	ES/H/0105/001	5999/2013/07	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg comprimato	ES/H/0105/001	5999/2013/08	J. URIACH & CÍA., S.A.	RO
Tamalis 10 mg tableta	ES/H/0105/001	OGYI-T-20788/01	J. URIACH & CÍA., S.A.	HU
Tamalis 10 mg tableta	ES/H/0105/001	OGYI-T-20788/02	J. URIACH & CÍA., S.A.	HU
Tamalis 10 mg tableta	ES/H/0105/001	OGYI-T-20788/03	J. URIACH & CÍA., S.A.	HU
Tamalis 10 mg tableta	ES/H/0105/001	OGYI-T-20788/04	J. URIACH & CÍA., S.A.	HU
TAMALIS 10 mg tablety	ES/H/0105/001	24/273/07-C	J. URIACH & CÍA., S.A.	CZ

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Urtimed 1 mg/ml Lösung zum Einnehmen	ES/H/0134/002	84257.00.00	BIOHORM, S.A.	DE
Urtimed® 10 mg Tabletten	ES/H/0134/001	68012.00.00	BIOHORM, S.A.	DE
WYSTAMM 1 mg/ml, solution buvable	ES/H/0105/002	222 560-2	J. URIACH & CÍA., S.A.	FR
WYSTAMM 10 mg, comprimé	ES/H/0105/001	61726688	J. URIACH & CÍA., S.A.	FR
Рупафин 1 mg/ml перорален разтвор	ES/H/0105/002	20130384	J. URIACH & CÍA., S.A.	BG
Рупафин 10 mg таблетки	ES/H/0105/001	20130385	J. URIACH & CÍA., S.A.	BG