



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/346098/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: rupatadine

Procedure no.: PSUSA/00002673/201506



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
Alergoliber	ES/H/0134/001	65350	Biohorm, S.A.	Spain
Alergoliber	ES/H/0134/002	222 559-4	Biohorm, S.A.	France
Alergoliber		34009 382 850 5 6 \$ 34009 382 881 1 7	Biohorm, S.A.	France
Alergoliber	ES/H/0134/002	75694	Biohorm, S.A.	Spain
Pafinur	ES/H/0105/001	31441	J. Uriach & Cía., S.A.	Finland
Pafinur	ES/H/0105/001	49269	J. Uriach & Cía., S.A.	Sweden
Pafinur	ES/H/0105/002	31442	J. Uriach & Cía., S.A.	Finland
Pafinur	ES/H/0105/002	49270	J. Uriach & Cía., S.A.	Sweden
Pafinur	ES/H/0134/001	0378880	Biohorm, S.A.	Italy
Pafinur	ES/H/0134/002	037888094	Biohorm, S.A.	Italy
Rinialer		65367	J. Uriach & Cía., S.A.	Spain
Rinialer		75990	J. Uriach & Cía., S.A.	Spain
Rinialer	ES/H/0105/001	MA004/00601	Bial - Portela & C ^a , Sa	Malta
Rinialer	ES/H/0105/001	3843588 \$ 3843687	Bialfar - Produtos Farmacêuticos, S.A.	Portugal
Rinialer	ES/H/0105/002	5453253	Bialfar - Produtos Farmacêuticos, S.A.	Portugal
Rinialer	ES/H/0105/002	MA004/00801	Bial - Portela & C ^a , Sa	Malta
Rupafin	ES/H/0105/001	037880	J. Uriach & Cía., S.A.	Italy
Rupafin	ES/H/0105/001	07-0302	J. Uriach & Cía., S.A.	Latvia
Rupafin	ES/H/0105/001	1-27273	J. Uriach & Cía., S.A.	Austria
Rupafin 10 mg	ES/H/0105/001	14244	J. Uriach & Cía., S.A.	Poland

Rupafin	ES/H/0105/001	20316	J. Uriach & Cía., S.A.	Cyprus
Rupafin	ES/H/0105/001	24/0148/07-S	J. Uriach & Cía., S.A.	Slovakia
Rupafin		52334 \$ 52335	J. Uriach & Cía., S.A.	Denmark
Rupafin	ES/H/0105/001	37818/29-05-2012	Olvos Science S.A.	Greece
Rupafin	ES/H/0105/001	H/08/01382/001-008	J. Uriach & Cía., S.A.	Slovenia
Rupafin	ES/H/0105/001	549607	J. Uriach & Cía., S.A.	Estonia
Rupafin	ES/H/0105/001	64.053	J. Uriach & Cía., S.A.	Spain
Rupafin	ES/H/0105/001	68011.00.00	J. Uriach & Cía., S.A.	Germany
Rupafin	ES/H/0105/001	LT/1/08/1006/001-008	J. Uriach & Cía., S.A.	Lithuania
Rupafin	ES/H/0105/001	PA 1129/1/1	J. Uriach & Cía., S.A.	Ireland
Rupafin	ES/H/0105/001	PL11906/0007	J. Uriach & Cía., S.A.	United Kingdom
Rupafin	ES/H/0105/001	RVG 34425	J. Uriach & Cía., S.A.	Netherlands
Rupafin	ES/H/0105/001	UP/I-530-09/13-01/29	J. Uriach & Cía., S.A.	Croatia
Rupafin	ES/H/0105/001-002/E/003	13/9498	J. Uriach & Cía., S.A.	Norway
Rupafin	ES/H/0105/001-002/E/003	139499	J. Uriach & Cía., S.A.	Norway
Rupafin	ES/H/0105/001-002/E/003	IS/1/13/066/01	J. Uriach & Cía., S.A.	Iceland
Rupafin	ES/H/0105/001-002/E/003	IS/1/13/066/02	J. Uriach & Cía., S.A.	Iceland
Rupafin	ES/H/0105/002	1-31463	J. Uriach & Cía., S.A.	Austria
Rupafin	ES/H/0105/002	12-0080	J. Uriach & Cía., S.A.	Latvia
Rupafin	ES/H/0105/002	20340	J. Uriach & Cía., S.A.	Poland

Rupafin	ES/H/0105/002	21571	J. Uriach & Cía., S.A.	Cyprus
Rupafin	ES/H/0105/002	24/0124/12-S	J. Uriach & Cía., S.A.	Slovakia
Rupafin	ES/H/0105/002	64809/26-8-2013	Olvos Science S.A.	Greece
Rupafin	ES/H/0105/002	75666	J. Uriach & Cía., S.A.	Spain
Rupafin	ES/H/0105/002	780212	J. Uriach & Cía., S.A.	Estonia
Rupafin	ES/H/0105/002	84256.00.00	J. Uriach & Cía., S.A.	Germany
Rupafin	ES/H/0105/002	LT/1/08/1006/009	J. Uriach & Cía., S.A.	Lithuania
Rupafin	ES/H/0105/002	PA 1129/001/002	J. Uriach & Cía., S.A.	Ireland
Rupafin	ES/H/0105/002	PL 11906/0009-0001	J. Uriach & Cía., S.A.	United Kingdom
Rupafin	ES/H/0105/002	RVG 108903	J. Uriach & Cía., S.A.	Netherlands
Rupafin	ES/H/0105/002/DC	H/08/01382/009	J. Uriach & Cía., S.A.	Slovenia
Rupatall	ES/H/0105/001	1528/11071198	J. Uriach & Cía., S.A.	Luxembourg
Rupatall	ES/H/0105/001	BE272045	J. Uriach & Cía., S.A.	Belgium
Rupatall	ES/H/0105/002	BE418153	J. Uriach & Cía., S.A.	Belgium
Tamalis	ES/H/0105/001	24/273/07-C	J. Uriach & Cía., S.A.	Czech Republic
Tamalis	ES/H/0105/001	6000/2013/01	J. Uriach & Cía., S.A.	Romania
Tamalis	ES/H/0105/001	OGYI-T-20788/01-04	J. Uriach & Cía., S.A.	Hungary
Tamalis	ES/H/0105/001-002/E/003	5999/2013/01-08	J. Uriach & Cía., S.A.	Romania
Tamalis	ES/H/0105/002	24/592/12-C	J. Uriach & Cía., S.A.	Czech Republic
Tamalis	ES/H/0105/002	OGYI-T-20788/05	J. Uriach & Cía., S.A.	Hungary

Urtimed	ES/H/0134/001	68012.00.00	Biohorm, S.A.	Germany
Urtimed	ES/H/0134/002	84257.00.00	Biohorm, S.A.	Germany
Wystamm	ES/H/0105/002	222 560-2	J. Uriach & Cía., S.A.	France
Wystamm		34009 382 884 0 7 \$ 34009 382 885 7 5 \$ 34009 384 158 5 8 \$ 34009 384 161 6 9 \$ 34009 384 159 1 9 \$ 34009 384 162 2 0 \$ 34009 572 215 2 2 \$ 34009 572 216 9 0	J. Uriach & Cía., S.A.	France
рупафин	ES/H/0105/001	20130385	J. Uriach & Cía., S.A.	Bulgaria
рупафин	ES/H/0105/002	20130384	J. Uriach & Cía., S.A.	Bulgaria