



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2019
EMA/27060/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: flunarizine

Procedure no.: PSUSA/00001416/201805



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
Flurpax 5 mg cápsulas duras	not available	56.129	TEOFARMA S.R.L.	ES
Flunagen 10 mg compresse	not available	024411035	VISUFARMA SPA	IT
Sibelium 5 mg comprimidos	not available	55.352	LABORATORIOS DR. ESTEVE S.A.	ES
Flunagen 5 mg capsule rigide	not available	024411023	VISUFARMA SPA	IT
FLUGERAL 10 mg capsule rigide 20 capsule	not available	024414043	Italfarmaco S.P.A	IT
FLUGERAL 10 mg capsule rigide 30 capsule	not available	024414056	Italfarmaco S.P.A	IT
FLUGERAL 10 mg capsule rigide 50 capsule	not available	024414068	Italfarmaco S.P.A	IT
FLUGERAL 5 mg capsule rigide 20 capsule	not available	024414017	Italfarmaco S.P.A	IT
FLUGERAL 5 mg capsule rigide 30 capsule	not available	024414029	Italfarmaco S.P.A	IT
FLUGERAL 5 mg capsule rigide 50 capsule	not available	024414031	Italfarmaco S.P.A	IT
GRADIENT Polifarma 5 mg capsule rigide	not available	024430023	Polifarma S.P.A	IT
GRADIENT Polifarma 10 mg capsule rigide	not available	024430035	Polifarma S.P.A	IT
SIBELIUM 10 mg tabletten	not available	BE109821	JANSSEN-CILAG NV	BE
Sibelium 10 mg Tabletten	not available	0162/98/11/5745	JANSSEN-CILAG NV	LU
Sibelium, filmovertrukne tabletter	not available	11216	JANSSEN-CILAG A/S	DK
Sibelium 10 mg tabletta	not available	OGYI-T-2174/01	JANSSEN-CILAG KFT.	HU
SIBELIUM 10 mg comprimés	not available	BE109821	JANSSEN-CILAG NV	BE
SIBELIUM 10 mg tabletten	not available	BE109821	JANSSEN-CILAG NV	BE
SIBELIUM 10 mg comprimés	not available	0162/98/11/5745	JANSSEN-CILAG NV	LU
Sibelium 10, tabletten 10 mg	not available	RVG 10579	JANSSEN-CILAG BV	NL
SIBELIUM 5 mg tablets	not available	20100133	JOHNSON & JOHNSON PRODAJA MEDICINSKIH IN FARMACEVTSKIH	BG

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
Flurpax 5 mg cápsulas duras	not available	56.129	TEOFARMA S.R.L.	ES
Flunagen 10 mg compresse	not available	024411035	VISUFARMA SPA	IT
Sibelium 5 mg comprimidos	not available	55.352	LABORATORIOS DR. ESTEVE S.A.	ES
			IZDELKOV, D.O.O.	
Sibelium 5 mg Tablets	not available	PA 748/31/2	JANSSEN-CILAG LIMITED	IE
Flerudin 5 mg comprimidos	not available	56.524	JANSSEN-CILAG S.A.	ES
Sibelium 5 mg δισκίο	not available	26301/14/17-09-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR
SIBELIUM 10 mg, comprimé sécable	not available	34009 328 294 4 6	JANSSEN-CILAG	FR
Sibelium 10 mg - Tabletten	not available	1-18443	JANSSEN-CILAG PHARMA GMBH	AT
Sibelium 5 mg cápsulas	not available	9519017	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sibelium 10 mg comprimidos	not available	9519132	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sibelium 5 mg Comprimidos	not available	5042411	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sibelium 5 mg Comprimidos	not available	5042403	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sibelium 10 mg comprimidos	not available	9519140	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
Sibelium 5 mg cápsulas	not available	9519009	JANSSEN FARMACÊUTICA PORTUGAL, LDA	PT
FLUXARTEN 10 mg capsule rigide	not available	024410021	FIDIA FARMACEUTICI S.P.A	IT
FLUXARTEN 5 mg capsule rigide	not available	024410045	FIDIA FARMACEUTICI S.P.A	IT