



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 January 2025
EMA/29529/2025
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: flunarizine

Procedure no.: PSUSA/00001416/202405



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
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
Flunagen 10 mg compresse	not available	024411035	VISUFARMA SPA	IT
Flunagen 10 mg compresse	not available	024411035	VISUFARMA SPA	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
Flunagen 5 mg capsule rigide	not available	024411023	VISUFARMA SPA	IT
Flunagen 5 mg capsule rigide	not available	024411023	VISUFARMA SPA	IT
Flurpax 5 mg cápsulas duras	not available	56.129	TEOFARMA S.R.L.	ES
FLUXARTEN 5 mg capsule rigide	not available	024410045	FIDIA FARMACEUTICI S.P.A	IT
FLUXARTEN 10 mg capsule rigide	not available	024410021	FIDIA FARMACEUTICI S.P.A	IT
GRADIENT POLIFARMA 10 mg capsule rigide	not available	024430035	POLIFARMA S.P.A	IT
GRADIENT POLIFARMA 5 mg capsule rigide	not available	024430023	POLIFARMA S.P.A	IT
Sibelium 10 mg - Tabletten	not available	1-18443	JANSSEN-CILAG PHARMA 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
Sibelium 10 mg comprimés	not available	BE109821	JANSSEN-CILAG NV	BE
SIBELIUM 10 mg comprimés	not available	0162/98/11/5745	JANSSEN-CILAG NV	LU
Sibelium 10 mg Tabletten	not available	BE109821	JANSSEN-CILAG NV	BE
Sibelium 10 mg tabletten	not available	BE109821	JANSSEN-CILAG NV	BE
Sibelium 10 mg Tabletten	not available	0162/98115745	JANSSEN-CILAG NV	LU
SIBELIUM 10 mg, comprimé sécable	not available	34009 328 294 4 6	JANSSEN-CILAG	FR
Sibelium 5 mg comprimidos	not available	55.352	ESTEVE PHARMACEUTICALS, S.A.	ES
Sibelium 5 mg comprimidos	not available	55.352	ESTEVE PHARMACEUTICALS, S.A.	ES

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SIBELIUM 5 mg δισκίο	not available	26301/14/17-09-2015	JANSSEN-CILAG PHARMACEUTICAL S.A.C.I.	GR