



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2023
EMA/163351/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): sodium tetradecyl sulphate

Procedure No.: PSUSA/00002767/202204



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
Fibrovein 0,2% soluzione iniettabile per uso endovenoso	not available	033012016	STD PHARMACEUTICAL (IRELAND) LTD	IT
Fibrovein 0,5% soluzione iniettabile per uso endovenoso	not available	033012028	STD PHARMACEUTICAL (IRELAND) LTD	IT
Fibrovein 1% soluzione iniettabile per uso endovenoso	not available	033012030	STD PHARMACEUTICAL (IRELAND) LTD	IT
Fibrovein 3% soluzione iniettabile per uso endovenoso	not available	033012042	STD PHARMACEUTICAL (IRELAND) LTD	IT
TROMBOVAR, injectie 1 %	not available	RVG 05447	LABORATOIRE KREUSSLER PHARMA	NL
TROMBOVAR, injectie 3 %	not available	RVG 05448	LABORATOIRE KREUSSLER PHARMA	NL
FIBROVEIN 0,2 %, solution injectable	CZ/H/0944/001	34009 268 825 9 4	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 0,2 %, solution injectable	CZ/H/0944/001	34009 268 823 6 5	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 0,5 %, solution injectable	CZ/H/0944/002	34009 268 826 5 5	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 1 %, solution injectable	CZ/H/0944/003	34009 268 832 5 6	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 3 %, solution injectable	CZ/H/0944/004	34009 268 833 1 7	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 0,2 %, solution injectable	CZ/H/0944/001	34009 268 824 2 6	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 3 %, solution injectable	CZ/H/0944/004	34009 268 834 8 5	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 3 %, solution injectable	CZ/H/0944/004	34009 268 833 4 6	STD PHARMACEUTICAL (IRELAND) LTD	FR
FIBROVEIN 3 %, solution injectable	CZ/H/0944/004	34009 268 836 0 7	STD PHARMACEUTICAL (IRELAND) LTD	FR
Фибровейн 0,2% инжекционен разтвор	CZ/H/0944/001	20170135	STD PHARMACEUTICAL (IRELAND) LTD	BG
Фибровейн 1% инжекционен разтвор	CZ/H/0944/003	20170137	STD PHARMACEUTICAL (IRELAND) LTD	BG
Фибровейн 0,5% инжекционен	CZ/H/0944/002	20170136	STD PHARMACEUTICAL	BG

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разтвор			(IRELAND) LTD	
Фибровейн 3% инжекционен разтвор	CZ/H/0944/004	20170138	STD PHARMACEUTICAL (IRELAND) LTD	BG
Fibrovein 0,2%, oplossing voor injectie	CZ/H/0944/001	RVG 119822	STD PHARMACEUTICAL (IRELAND) LTD	NL
Fibrovein 0,5%, oplossing voor injectie	CZ/H/0944/002	RVG 119829	STD PHARMACEUTICAL (IRELAND) LTD	NL
Fibrovein 1%, oplossing voor injectie	CZ/H/0944/003	RVG 119830	STD PHARMACEUTICAL (IRELAND) LTD	NL
Fibrovein 3%, oplossing voor injectie	CZ/H/0944/004	RVG 119831	STD PHARMACEUTICAL (IRELAND) LTD	NL
Veinfibro 0,2 % Injektionslösung	CZ/H/0944/001	137624	STD PHARMACEUTICAL (IRELAND) LTD	AT
Veinfibro 0,5 % Injektionslösung	CZ/H/0944/002	137625	STD PHARMACEUTICAL (IRELAND) LTD	AT
Veinfibro 1% Injektionslösung	CZ/H/0944/003	137626	STD PHARMACEUTICAL (IRELAND) LTD	AT
Veinfibro 3 % Injektionslösung	CZ/H/0944/004	137627	STD PHARMACEUTICAL (IRELAND) LTD	AT
Fibrovein, 1%, roztwór do wstrzykiwań	CZ/H/0944/003	24035	STD PHARMACEUTICAL (IRELAND) LTD	PL
Fibrovein, 3%, roztwór do wstrzykiwań	CZ/H/0944/004	24036	STD PHARMACEUTICAL (IRELAND) LTD	PL
Fibrovein, 0,2%, roztwór do wstrzykiwań	CZ/H/0944/001	24033	STD PHARMACEUTICAL (IRELAND) LTD	PL
Fibrovein, 0,5%, roztwór do wstrzykiwań	CZ/H/0944/002	24034	STD PHARMACEUTICAL (IRELAND) LTD	PL
Fibrovein 2 mg/ml raztopina za injiciranje	CZ/H/0944/001	H/17/02381/002	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 2 mg/ml raztopina za injiciranje	CZ/H/0944/001	H/17/02381/003	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 2 mg/ml raztopina za injiciranje	CZ/H/0944/001	H/17/02381/001	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 30 mg/ml raztopina za injiciranje	CZ/H/0944/004	H/17/02381/006	STD PHARMACEUTICAL (IRELAND) LTD	SI

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Fibrovein 5 mg/ml raztopina za injiciranje	CZ/H/0944/002	H/17/02381/004	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 10 mg/ml raztopina za injiciranje	CZ/H/0944/003	H/17/02381/005	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 30 mg/ml raztopina za injiciranje	CZ/H/0944/004	H/17/02381/008	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 30 mg/ml raztopina za injiciranje	CZ/H/0944/004	H/17/02381/009	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 30 mg/ml raztopina za injiciranje	CZ/H/0944/004	H/17/02381/007	STD PHARMACEUTICAL (IRELAND) LTD	SI
Fibrovein 0,2% soluție injectabilă	CZ/H/0944/001	10787/2018/01	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 0,2% soluție injectabilă	CZ/H/0944/001	10787/2018/02	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 0,2% soluție injectabilă	CZ/H/0944/001	10787/2018/03	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 0,5% soluție injectabilă	CZ/H/0944/002	10788/2018/01	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 1% soluție injectabilă	CZ/H/0944/003	10789/2018/01	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 3% soluție injectabilă	CZ/H/0944/004	10790/2018/01	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 3% soluție injectabilă	CZ/H/0944/004	10790/2018/02	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 3% soluție injectabilă	CZ/H/0944/004	10790/2018/03	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 3% soluție injectabilă	CZ/H/0944/004	10790/2018/04	STD PHARMACEUTICAL (IRELAND) LTD	RO
Fibrovein 2 mg/ml Injekční roztok	CZ/H/0944/001	85/706/12-C	STD PHARMACEUTICAL (IRELAND) LTD	CZ
Fibrovein 5 mg/ml Injekční roztok	CZ/H/0944/002	85/707/12-C	STD PHARMACEUTICAL (IRELAND) LTD	CZ
Fibrovein 10 mg/ml Injekční roztok	CZ/H/0944/003	85/708/12-C	STD PHARMACEUTICAL (IRELAND) LTD	CZ
Fibrovein 30 mg/ml Injekční	CZ/H/0944/004	85/709/12-C	STD PHARMACEUTICAL	CZ

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roztok			(IRELAND) LTD	
Veinfibro 0,2 % solución inyectable	CZ/H/0944/001	77024	STD PHARMACEUTICAL (IRELAND) LTD	ES
Veinfibro 0,5 % solución inyectable	CZ/H/0944/002	77025	STD PHARMACEUTICAL (IRELAND) LTD	ES
Veinfibro 1 % solución inyectable	CZ/H/0944/003	77026	STD PHARMACEUTICAL (IRELAND) LTD	ES
Veinfibro 3 % solución inyectable	CZ/H/0944/004	77027	STD PHARMACEUTICAL (IRELAND) LTD	ES
TROMBOVAR 1 POUR CENT I.V., solution injectable	not available	34009 491 198 0 6	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	FR
TROMBOVAR 3 POUR CENT I.V., solution injectable	not available	34009 491 199 7 4	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	FR
TROMBOVAR 1 POUR CENT I.V., solution injectable	not available	34009 310 867 2 7	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	FR
TROMBOVAR 3 POUR CENT I.V., solution injectable	not available	34009 310 868 9 5	CHEMISCHE FABRIK KREUSSLER & CO. GMBH	FR