



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2018
EMA/35069/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: sodium tetradecyl sulphate

Procedure no.: PSUSA/00002767/201704



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
Veinfibro 0,2 % Injektionslösung	UK/H/2775/001	137624	STD PHARMACEUTICAL PRODUCTS LTD	AT
Veinfibro 0,5 % Injektionslösung	UK/H/2775/002	137625	STD PHARMACEUTICAL PRODUCTS LTD	AT
Veinfibro 1 % Injektionslösung	UK/H/2775/003	137626	STD PHARMACEUTICAL PRODUCTS LTD	AT
Veinfibro 3 % Injektionslösung	UK/H/2775/004	137627	STD PHARMACEUTICAL PRODUCTS LTD	AT
Фибровейн 0,2 % инжекционен разтвор	UK/H/2775/001	20170135	STD PHARMACEUTICAL PRODUCTS LTD	BG
Фибровейн 1% инжекционен разтвор	UK/H/2775/003	20170137	STD PHARMACEUTICAL PRODUCTS LTD	BG
Фибровейн 0,5 % инжекционен разтвор	UK/H/2775/002	20170136	STD PHARMACEUTICAL PRODUCTS LTD	BG
Фибровейн 3% инжекционен разтвор	UK/H/2775/004	20170138	STD PHARMACEUTICAL PRODUCTS LTD	BG
Fibrovein 2 mg/ml Solution for Injection Injekční roztok	UK/H/2775/001	85/706/12-C	STD PHARMACEUTICAL PRODUCTS LTD	CZ
Fibrovein 5 mg/ml Solution for Injection Injekční roztok	UK/H/2775/002	85/707/12-C	STD PHARMACEUTICAL PRODUCTS LTD	CZ
Fibrovein 10 mg/ml Solution for Injection Injekční roztok	UK/H/2775/003	85/708/12-C	STD PHARMACEUTICAL PRODUCTS LTD	CZ
Fibrovein 30 mg/ml Solution for Injection Injekční roztok	UK/H/2775/004	85/709/12-C	STD PHARMACEUTICAL PRODUCTS LTD	CZ
Veinfibro 0,2 % solución inyectable	UK/H/2775/001	77024	STD PHARMACEUTICAL PRODUCTS LTD	ES
Veinfibro 0,5 % solución inyectable	UK/H/2775/002	77025	STD PHARMACEUTICAL PRODUCTS LTD	ES
Veinfibro 1 % solución inyectable	UK/H/2775/003	77026	STD PHARMACEUTICAL PRODUCTS LTD	ES

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Veinfibro 3 % solución inyectable	UK/H/2775/004	77027	STD PHARMACEUTICAL PRODUCTS LTD	ES
TROMBOVAR 1 POUR CENT I.V., solution injectable	not available	3400949119806	LABORATOIRE KREUSSLER PHARMA	FR
TROMBOVAR 3 POUR CENT I.V., solution injectable	not available	3400949119974	LABORATOIRE KREUSSLER PHARMA	FR
TROMBOVAR 1 POUR CENT I.V., solution injectable	not available	3400931086727	LABORATOIRE KREUSSLER PHARMA	FR
TROMBOVAR 3 POUR CENT I.V., solution injectable	not available	3400931086895	LABORATOIRE KREUSSLER PHARMA	FR
FIBROVEIN 0,2 %, solution injectable	UK/H/2775/001	268 823-6	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,5 %, solution injectable	UK/H/2775/002	268 826-5	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 1 %, solution injectable	UK/H/2775/003	268 832-5	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	268 833-1	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,2 %, solution injectable	UK/H/2775/001	268 824-2	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,2 %, solution injectable	UK/H/2775/001	34009 268 825 9 4	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,2 %, solution injectable	UK/H/2775/001	34009 268 823 6 5	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,2 %, solution injectable	UK/H/2775/001	268 825-9	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,5 %, solution injectable	UK/H/2775/002	34009 268 826 5 5	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 1 %, solution injectable	UK/H/2775/003	34009 268 832 5 6	STD PHARMACEUTICAL PRODUCTS LTD	FR

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FIBROVEIN 3 %, solution injectable	UK/H/2775/004	34009 268 833 1 7	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 0,2 %, solution injectable	UK/H/2775/001	34009 268 824 2 6	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	268 834-8	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	34009 268 834 8 5	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	268 835-4	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	34009 268 835 4 6	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	268 836-0	STD PHARMACEUTICAL PRODUCTS LTD	FR
FIBROVEIN 3 %, solution injectable	UK/H/2775/004	34009 268 836 0 7	STD PHARMACEUTICAL PRODUCTS LTD	FR
Fibrovein 0,2% otopina za injekciju	UK/H/2775/001	HR-H-225449690	STD PHARMACEUTICAL PRODUCTS LTD	HR
Fibrovein 0,5% otopina za injekciju	UK/H/2775/002	HR-H-684965032	STD PHARMACEUTICAL PRODUCTS LTD	HR
Fibrovein 1% otopina za injekciju	UK/H/2775/003	HR-H-545950856	STD PHARMACEUTICAL PRODUCTS LTD	HR
Fibrovein 3% otopina za injekciju	UK/H/2775/004	HR-H-678690592	STD PHARMACEUTICAL PRODUCTS LTD	HR
Fibro-Vein 2 mg/ml oldatos injekció	not available	OGYI-T-5896/01	STD PHARMACEUTICAL PRODUCTS LTD	HU
Fibro-Vein 5 mg/ml oldatos injekció	not available	OGYI-T-5896/02	STD PHARMACEUTICAL PRODUCTS LTD	HU
Fibro-Vein 10 mg/ml oldatos injekció	not available	OGYI-T-5896/03	STD PHARMACEUTICAL PRODUCTS LTD	HU
Fibro-Vein 30 mg/ml oldatos injekció	not available	OGYI-T-5896/04	STD PHARMACEUTICAL PRODUCTS LTD	HU
Fibro-Vein 30 mg/ml oldatos injekció	not available	OGYI-T-5896/05	STD PHARMACEUTICAL PRODUCTS LTD	HU

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Fibro-Vein 0.2% w/v Solution for Injection	not available	PA 0246/001/007	STD PHARMACEUTICAL PRODUCTS LTD	IE
Fibro-Vein 0.5% w/v Solution for Injection	not available	PA 0246/001/003	STD PHARMACEUTICAL PRODUCTS LTD	IE
Fibro-Vein 1.0% w/v Solution for Injection	not available	PA 0246/001/004	STD PHARMACEUTICAL PRODUCTS LTD	IE
Fibro-Vein 3.0% w/v Solution for Injection	not available	PA 0246/001/005	STD PHARMACEUTICAL PRODUCTS LTD	IE
Fibro-Vein 3.0% w/v Solution for Injection (5ml vial)	not available	PA 0246/001/006	STD PHARMACEUTICAL PRODUCTS LTD	IE
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%, oplossing voor injectie	UK/H/2775/001	RVG 119822	STD PHARMACEUTICAL PRODUCTS LTD	NL
Fibrovein 0,5%, oplossing voor injectie	UK/H/2775/002	RVG 119829	STD PHARMACEUTICAL PRODUCTS LTD	NL
Fibrovein 1%, oplossing voor injectie	UK/H/2775/003	RVG 119830	STD PHARMACEUTICAL PRODUCTS LTD	NL
Fibrovein 3%, oplossing voor injectie	UK/H/2775/004	RVG 119831	STD PHARMACEUTICAL PRODUCTS LTD	NL
Fibrovein, 1%, roztwór do wstrzykiwań	UK/H/2775/003	24035	STD PHARMACEUTICAL PRODUCTS LTD	PL
Fibrovein, 3%, roztwór do wstrzykiwań	UK/H/2775/004	24036	STD PHARMACEUTICAL PRODUCTS LTD	PL
Fibrovein, 0,2%, roztwór do wstrzykiwań	UK/H/2775/001	24033	STD PHARMACEUTICAL PRODUCTS LTD	PL
Fibrovein, 0,5%, roztwór do wstrzykiwań	UK/H/2775/002	24034	STD PHARMACEUTICAL PRODUCTS LTD	PL
Fibrovein 0,2% Solução Injectável	UK/H/2775/001	5564604	STD PHARMACEUTICAL PRODUCTS LTD	PT

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Fibrovein 0,2% Solução Injectável	UK/H/2775/001	5564612	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 0,2% Solução Injectável	UK/H/2775/001	5564620	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 0,5% Solução Injectável	UK/H/2775/002	5564638	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 1% Solução Injectável	UK/H/2775/003	5564646	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 3% Solução Injectável	UK/H/2775/004	5564653	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 3% Solução Injectável	UK/H/2775/004	5564703	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 3% Solução Injectável	UK/H/2775/004	5564661	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 3% Solução Injectável	UK/H/2775/004	5564679	STD PHARMACEUTICAL PRODUCTS LTD	PT
Fibrovein 0,2% soluție injectabilă	UK/H/2775/001	9903/2017/01	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 0,5% soluție injectabilă	UK/H/2775/002	9904/2017/01	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 1% soluție injectabilă	UK/H/2775/003	9905/2017/01	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 3% soluție injectabilă	UK/H/2775/004	9906/2017/01	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 0,2% soluție injectabilă	UK/H/2775/001	9903/2017/02	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 0,2% soluție injectabilă	UK/H/2775/001	9903/2017/03	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 3% soluție injectabilă	UK/H/2775/004	9906/2017/02	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 3% soluție injectabilă	UK/H/2775/004	9906/2017/03	STD PHARMACEUTICAL PRODUCTS LTD	RO
Fibrovein 3% soluție injectabilă	UK/H/2775/004	9906/2017/04	STD PHARMACEUTICAL PRODUCTS LTD	RO

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FIBRO-VEIN 0,2%	not available	85/0287/03-S	STD PHARMACEUTICAL PRODUCTS LTD	SK
FIBRO-VEIN 3%	not available	85/0341/00-S	STD PHARMACEUTICAL PRODUCTS LTD	SK
Fibrovein 0.2% Solution for Injection	UK/H/2775/001	PL 00398/0204	STD PHARMACEUTICAL PRODUCTS LTD	UK
Fibrovein 0.5% Solution for Injection	UK/H/2775/002	PL 00398/0205	STD PHARMACEUTICAL PRODUCTS LTD	UK
Fibrovein 1% Solution for Injection	UK/H/2775/003	PL 00398/0206	STD PHARMACEUTICAL PRODUCTS LTD	UK
Fibrovein 3% Solution for Injection	UK/H/2775/004	PL 00398/0207	STD PHARMACEUTICAL PRODUCTS LTD	UK