

Prescribing Information

NAME OF PRODUCT:

FIBRO-VEIN™ 3%, 1%, 0.5%, 0.2%

PRESENTATION

FIBRO-VEIN is a sterile aqueous solution of sodium tetradecyl sulphate available in four strengths 3%, 1%, 0.5% and 0.2% each containing 2% benzyl alcohol and buffered to pH7.6.

USES

The solution is designed for intravenous use as a sclerosant in the treatment of varicose veins of the leg by compression sclerotherapy. The action of sodium tetradecyl sulphate in this technique is considered to be that of irritation to the intima of the vein wall, so that on compression of the vein, fibrosis takes place and the vein is permanently occluded by the development of fibrosis in the wall of the compressed vein.

DOSAGE AND ADMINISTRATION ADULTS AND THE ELDERLY (NOT RECOMMENDED FOR USE IN CHILDREN)

FIBRO-VEIN 3%.

Dosage 0.5-1ml at each of four sites (maximum 4ml). A dose of 0.5 to 1ml of FIBRO-VEIN 3% is injected intravenously into the lumen of an isolated segment of emptied superficial vein, followed by immediate continuous compression. A maximum of four sites (4ml total) may be injected during one treatment session.

FIBRO-VEIN 1%.

Dosage 0.25-1ml at each of 10 sites (maximum 10ml) The uses and principles behind the treatment using FIBRO-VEIN 1% is the same as described for FIBRO-VEIN 3%. However the injection is designed for the treatment of small varicose veins and the larger venules by the empty vein technique.

FIBRO-VEIN 0.5%.

Dosage 0.25-1ml at each of 10 sites (maximum 10ml). FIBRO-VEIN 0.5% is produced specifically for the treatment by sclerotherapy of medium venules.

FIBRO-VEIN 0.2%.

Dosage 0.1-1ml at each of 10 sites (maximum 10ml). FIBRO-VEIN 0.2% is produced specifically for the treatment of minor venules and spider veins (*Venous Flares*).

CONTRA-INDICATION, WARNINGS, ETC.

The use of FIBRO-VEIN is not recommended for the treatment of varicose veins by compression sclerotherapy when any of the following factors are present: Allergy to sodium tetradecyl sulphate or any component of the preparation. Patients unable to walk due to any cause. Patients currently taking oral contraceptives. Significant obesity. Acute superficial thrombophlebitis. Local or systemic infection. Varicosities caused by pelvic or abdominal tumours. Uncontrolled systemic disease e.g. diabetes mellitus. Significant valvular incompetence requiring surgical treatment. Cardiac failure. Pulmonary oedema.

Side effects

1. *Local*: Pain or burning. Skin pigmentation. Tissue necrosis and ulceration may occur with extravasation. Paraesthesia and anaesthesia may occur if an injection affects a cutaneous nerve.
2. *Vascular*: Superficial thrombophlebitis. Deep vein thrombosis and pulmonary embolism are very rare. Inadvertent intra-arterial injection is very rare but may lead to gangrene. Most cases have involved the posterior tibial artery above the medial malleolus.
3. *Systemic reactions*: Allergic reactions are rare, presenting as local or generalised rash, urticaria, nausea or vomiting, asthma, vascular collapse. Anaphylactic shock, which may potentially be fatal, is extremely rare.

Use in pregnancy and lactation

Safety for use in pregnancy has not been established. Use only when clearly needed for symptomatic relief and when the potential benefits outweigh the potential hazards to the foetus. It is not known whether sodium tetradecyl sulphate is excreted in human milk. Caution should be exercised when used in nursing mothers.

Special warnings and precautions

FIBRO-VEIN should only be administered by practitioners familiar with an acceptable injection technique. Thorough pre-injection assessment for valvular competence and deep vein patency must be carried out. Extreme care in needle placement and slow injection of the minimal effective volume at each injection site are essential for safe and efficient use.

1. Allergy and Anaphylaxis

- a) History of allergy should be taken from all patients prior to treatment. In particular, allergic reactions to previous injections of sodium tetradecyl sulphate should be noted (see contra-indications above).
- b) A higher incidence of allergic reaction is thought to result from repeated treatment involving sodium tetradecyl sulphate injection and may involve intervals of several years between courses of injections.
- c) Where special caution is indicated a test dose of 0.25 to 0.5ml FIBRO-VEIN should be given up to 24hrs before any further therapy.

2. Equipment of the clinic. The Treatment of anaphylaxis may require, depending on the severity of attack, some or all of the following: Injection of adrenaline (epinephrine), injection of hydrocortisone, injection of antihistamine, endotracheal tube, laryngoscope and mucous extraction pump. The treatment of varicose veins by FIBRO-VEIN should not be undertaken in clinics where these items are not readily available.

3. Special care is required when injecting above and posterior to the medial malleolus where extra-vascular injection is in danger of being close to the posterior and tibial artery.

4. Pigmentation can result if blood is extravasated at the injection site (particularly when treating smaller surface veins) and compression is not used.

5. Extreme caution in use is required in patients with arterial disease such as severe peripheral atherosclerosis or thromboangiitis obliterans (*Buerger's disease*).

Information about adverse event reporting in the UK can be found at www.yellowcard.gov.uk. Adverse events should also be reported to STD Pharmaceutical Products Ltd.

PHARMACEUTICAL PRECAUTIONS

Do not store above 25°C, Store away from direct sunlight. The in use period of each 5ml multidose vial is a single session of therapy and for use in the treatment of a single patient. Unused vial contents should be discarded immediately afterwards.

LEGAL CATEGORY: Prescription only.

PACKAGE QUANTITIES & UK NHS COST

Fibro-Vein 3% 10 x 5ml Vials £102.50.
Fibro-Vein 3% 5 x 2ml Ampoules £20.37.
Fibro-Vein 1% 5 x 2ml Ampoules £16.56.
Fibro-Vein 0.5% 5 x 2ml Ampoules £14.35.
Fibro-Vein 0.2% 10 x 5ml Vials £55.09.

FURTHER INFORMATION

The use of a small dose, the isolation of the injection within the vein segment and the application of immediate, adequate and lasting compression are of supreme importance in obtaining a good result.

PRODUCT LICENCE NUMBERS

Fibro-Vein 3% 5ml PL 0398/5000
Fibro-Vein 1% 2ml PL 0398/0003
Fibro-Vein 0.5% 2ml PL 0398/0002
Fibro-Vein 0.2% 5ml PL 0398/0004

SOLD AND SUPPLIED BY:

STD Pharmaceutical Products Ltd.,
Plough Lane, Hereford HR4 0EL, England.
Tel: 01432 373555 Fax: 01432 373556
Email: enquiries@stdpharm.co.uk

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Fibro-Vein & STD are registered Trade Marks.