

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fibro-Vein 0.5% w/v Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains sodium tetradecyl sulfate 0.5% w/v (equivalent to 5 mg/ml).

Excipients: Contains benzyl alcohol 20 mg/ml, sodium 2.43 mg/ml and potassium 0.29 mg/ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of varicose veins and venous flares of the leg by injection sclerotherapy.

4.2 Posology and method of administration

Route of Administration

For intravenous administration into the lumen of an isolated segment of emptied vein followed by immediate continuous compression.

Recommended doses and dosage schedules

Adults
0.25 to 1.0ml of 0.5% fibro-vein injected intravenously at a maximum of 10 sites (maximum 10ml).

Children
Not recommended in children.

Elderly
As for adults.

4.3 Contraindications

1. Allergy to sodium tetradecyl sulfate or to any component of the preparation.
2. Patients unable to walk due to any cause.
3. Patients currently taking oral contraceptives.
4. Significant obesity.
5. Acute superficial thrombophlebitis.
6. Local or systemic infection.
7. Varicosities caused by pelvic or abdominal tumours.

8. Uncontrolled systemic disease e.g. diabetes mellitus.
9. Significant valvular incompetence requiring surgical treatment.

4.4 Special warnings and precautions for use

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.

A history of allergy should be taken from all patients prior to treatment. Where special caution is indicated a test dose of 0.25 to 0.5 ml fibro-vein should be given up to 24 hours before any further therapy.

Treatment of anaphylaxis may require, depending on the severity of attack, some or all of the following: injection of adrenaline, injection of hydrocortisone, injection of antihistamine, endotracheal intubation with use of a laryngoscope and suction.

The treatment of varicose veins by fibro-vein should not be undertaken in clinics where these items are not readily available.

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

Special care is required when injection above and posterior to the medial malleolus where the posterior tibial artery may be at risk.

Pigmentation may be more likely to result if blood is extravasated at the injection site (particularly when treating smaller surface veins) and compression is not used).

4.5 Interaction with other medicinal products and other forms of interactions

Do not use with heparin in the same syringe.

4.6 Fertility, 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 sulfate is excreted in human milk. Caution should be exercised when used in nursing mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Local

Pain or burning. Skin pigmentation. Tissue necrosis and ulceration may occur with extravasation. Paraesthesia and anaesthesia may occur if an injection effects a cutaneous nerve.

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.

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.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Therapeutic group: Anti-varicose therapy – sclerosants for local action

ATC Code: CO5B B04

Sodium tetradecyl sulfate damages the endothelium cells within the lumen of the injected vein. The object of compression sclerotherapy is then to compress the vein so that the resulting thrombus is kept to the minimum and the subsequent formation of scar tissue within the vein produces a fibrous cord and permanent obliteration. Non-compressed veins permit the formation of a large thrombus and produce less fibrosis within the vein.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Disodium phosphate, anhydrous
Potassium dihydrogen phosphate
Water for injection
Sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

Do not use with heparin in the same syringe.

6.3 Shelf life

Unopened: 3 years.

Once opened, use immediately and discard any remaining solution.

6.4 Special precautions for storage

Do not store above 25°C. Keep the ampoules in the outer carton.

6.5 Nature and contents of container

Ph. Eur. Type 1 glass ampoule.

Pack size: 5 x 2ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Each glass ampoule is for single use only.

Any unused contents must be discarded.

7 MARKETING AUTHORISATION HOLDER

STD Pharmaceutical (Ireland) Limited
Block 1
Blanchardstown Corporate Park
Ballycoolen Road
Blanchardstown
Dublin 15
D15 AKK1
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22778/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th May 2001

Date of last renewal: 4th May 2006

10 DATE OF REVISION OF THE TEXT

June 2019