

New Zealand Datasheet

Name of Medicine

FIBRO-VEIN

Sodium Tetradecyl Sulphate 3.0%, 1.0%, 0.5% and 0.2% intravenous injection

Presentation

Fibro-vein 3.0%: Sodium Tetradecyl Sulphate BP 3.0% w/v

Fibro-vein 1.0%: Sodium Tetradecyl Sulphate BP 1.0% w/v

Fibro-vein 0.5%: Sodium Tetradecyl Sulphate BP 0.5% w/v

Fibro-vein 0.2%: Sodium Tetradecyl Sulphate BP 0.2% w/v

Uses

Actions

Pharmacodynamic properties: Sodium tetradecyl sulphate 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.

Pharmacokinetics

Not applicable

Indications

Fibro-vein 3% and 1%: For the treatment of varicose veins of the leg by injection sclerotherapy.

Fibro-vein 0.5%: For the treatment of varicose veins and venous flares of the leg by injection sclerotherapy.

Fibro-vein 0.2%: For the treatment of minor venules and spider veins (venous flares) by injection sclerotherapy.

Dosage and 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

Fibro-vein 3.0%: 0.5 to 1.0ml of 3.0% Fibro-vein injected intravenously at each of 4 sites (maximum 4ml).

Fibro-vein 1.0%: 0.25 to 1.0ml of 1.0% Fibro-vein injected intravenously into the lumen of an isolated segment of emptied superficial vein, followed by immediate compression. A maximum of 10 sites (10ml total) may be injected during one treatment session.

Fibro-vein 0.5%: 0.25 to 1.0ml of 0.5% Fibro-vein injected intravenously into the lumen of an isolated segment of emptied superficial vein, followed by immediate compression. A maximum of 10 sites (10ml total) may be injected during one treatment session.

Fibro-vein 0.2%: 0.1 to 1.0ml of 0.2% Fibro-vein injected intravenously at each of 10 sites (maximum 10ml).

The smallest of needles (30 gauge) should be used to perform the injection, which should be made slowly so that the blood content of these veins is expelled. In the treatment of spider veins an air block technique may be used.

Children

All strengths: not recommended in children

The Elderly

As for adults.

Contraindications

- Allergy to sodium tetradecyl sulphate or to any component of the preparation.
- Patients unable to walk due to any cause.
- Patients currently taking oral contraceptives or hormone replacement therapy.
- Significant obesity.
- Acute superficial thrombophlebitis.
- Local or systemic infection.
- Varicosities caused by pelvic or abdominal tumours.
- Uncontrolled systemic disease e.g. diabetes mellitus.
- Surgical valvular incompetence requiring surgical treatment.

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.

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 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 thromboangitis obliterans (Buerger's Disease).

Special care is required when injecting 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.

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.

Effects on Ability to Drive and to Use Machines

None known.

Adverse Effects

Local: Pain and 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.

Interactions

Do not use with heparin in the same syringe.

Overdose

Not applicable

Pharmaceutical Precautions

Store below 25°C away from direct sunlight.

Package quantities

Fibro-vein 3.0%: 2ml ampoules and 5ml vials

Fibro-vein 1.0%: 2ml ampoules

Fibro-vein 0.5%: 2ml ampoules

Fibro-vein 0.2%: 5ml vials.

Medicine Classification

Prescription medicine

Further Information

List of excipients

Benzyl Alcohol BP, Disodium Hydrogen Phosphate BP, Potassium dihydrogen phosphate analar, Water for injections BP.

Incompatibilities:

Do not use with heparin in the same syringe.

Instructions for use/handling

Each 2ml glass ampoule is for single use only. The in use period of each 5ml multi-dose 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.

Shelf life

36 months

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Date of Preparation

2 October 2003