

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Fibro-Vein 1.0% w/v Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains sodium tetradecyl sulfate 1.0% w/v (equivalent to 10 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 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 1.0 % 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 2 ml 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**

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**8 MARKETING AUTHORISATION NUMBER**

PA22778/001/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

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Date of last renewal: 4<sup>th</sup> May 2006

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