

**PACKAGE LEAFLET:  
INFORMATION FOR THE USER**

**Fibro-Vein 0.2% w/v, 0.5% w/v, 1% w/v and 3% w/v  
Solution for Injection  
Sodium tetradecyl sulphate**

**Read all of this leaflet carefully before you are given this injection.**

- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Fibro-Vein Injection is and what it is used for
2. Before you are given Fibro-Vein Injection
3. Your treatment with Fibro-Vein Injection
4. Possible side effects
5. How to store Fibro-Vein Injection
6. Further information

**1. What Fibro-Vein Injection is and what it is used for**

The name of your medicine is Fibro-Vein Injection, which contains the active ingredient sodium tetradecyl sulphate.

This injection belongs to a group of medicines called sclerosants. Sclerosants are chemical agents, when injected into the affected vein causes the lining of the vein walls to swell and the walls stick together. This stops the flow of blood and the vein turns into scar tissue. In a few weeks, the vein should fade.

Different strengths of Fibro-Vein Injection are used in the treatment of varicose veins, minor venules and spider veins.

**2. Before you take Fibro-Vein Injection**

**You should not take Fibro-Vein Injection if you:**

- are allergic (hypersensitive) to sodium tetradecyl sulphate or to any of the other ingredients in Fibro-Vein Injection (see section 6, Further information)
- cannot walk due to any reason
- have severe inflammation of veins in the legs (acute phlebitis)
- have blood clots in your veins (thrombosis)
- have twisted veins (varicose veins) caused by pelvic or abdominal tumours
- are significantly overweight
- have any kind of infection
- have diabetes which is uncontrolled
- have surgical heart disease requiring surgical treatment.

**Talk to your doctor before taking Fibro-Vein Injection if you:**

- have been told that you have any disease of your arteries or veins (atherosclerosis)
- have been told a surgical treatment is required to correct a valve in the blood vessel
- have severe inflammation and clotting of arteries and veins affecting the hands and feet (Buerger's disease)
- have heart disease.

If you are allergic to any food or medicine, you should speak to the doctor before being given this injection, so that a test dose can be given 24 hours before any further therapy.

Treatment with Fibro-Vein Injection must not be undertaken in clinics which do not have the facilities (injections like adrenaline, hydrocortisone, antihistamine, endotracheal tubation with use of a laryngoscope and suction) to treat a severe allergic reaction (anaphylactic shock).

Special care must be taken when injecting above and below the ankle due to risk to one of the arteries.

**Taking other medicines**

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following medicines can affect or be affected by treatment with Fibro-Vein Injection:

- oral contraceptive pills
- heparin (a medicine used to stop formation of blood clots) should not be administered in the same syringe.

**Pregnancy and breast-feeding**

If you are pregnant or think you may be pregnant or breast feeding please speak with your doctor before being given this injection.

**Driving and using machinery**

After the treatment with this injection, you may be told to wear a bandage and or/ compression stockings to help reduce inflammation and pigmentation of the skin which could affect your ability to drive.

**Important Information about some of the ingredients of Fibro-Vein**

This medicine contains potassium, less than 1 mmol (39mg) per dose, i.e. essentially "potassium-free". This medicinal product contains sodium (max. 150mg) per treatment. To be taken into consideration by patients on a controlled sodium diet.

**3. Treatment with Fibro-Vein Injection**

You **MUST NOT** try to inject Fibro-Vein yourself. You should always be treated by an experienced doctor who is familiar with the injection technique.

The therapy involves injecting the medicine into the affected vein using the smallest of needles and it is to be injected slowly and with extreme care so that the blood content of these veins is expelled.

Your doctor will decide on the areas to treat and the right dose for you. The usual doses are as follows:

**Adults and the elderly**

- varies between 0.1 and 1ml for each injection. A maximum of 10ml of the three lower strength injections may be used, however no more than 4ml is used when the strongest injection is used.

**Children**

- Fibro-Vein Injection is not recommended for children.

After you have been treated with Fibro-Vein Injection, you should follow your doctor's advice. You may be told to wear a bandage and or/compression stockings to help reduce inflammation and pigmentation of the skin.

#### 4. Possible side effects

Like all medicines, Fibro-Vein Injection can cause side effects, although not everybody gets them.

- pain
- burning sensation
- skin pigmentation
- discolouration of the skin
- tingling or numbness
- tissue damage if the injection is outside the vein
- blood clots causing inflammation on the surface of the skin
- very rarely clots may be formed in the lungs (pulmonary embolism) or in deep in the veins (deep vein thrombosis)
- accidental injection into an artery is very rare but may lead to death of tissue and cells below injection site (gangrene).

As can happen with any medicine, a few people may develop an allergic reaction causing

- rash
- itching red skin
- nausea
- vomiting
- difficulty breathing
- feeling faint.

A very severe form of allergic reaction (anaphylactic shock) is extremely rare but should be treated immediately which otherwise may be fatal.

If you experience any serious side effects or feel that the medicine is affecting you badly tell your doctor or pharmacist immediately.

#### 5. How to store Fibro-Vein Injection

For single use only.

Keep out the reach and sight of children.

- Do not store above 25°C
- Keep the vials and ampoules in the outer carton
- Fibro-Vein Injection should not be used after the expiry date given on the carton; the expiry date refers to the last day of the month.

Once opened, use immediately and discard any remaining solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

#### 6. Further information

##### What Fibro-Vein Injection contains

The active ingredient is: sodium tetradecyl sulphate and is available in 4 strengths: 2mg/ml, 5mg/ml, 10mg/ml and 30mg/ml.

The other ingredients are: benzyl alcohol, disodium phosphate anhydrous, potassium dihydrogen phosphate, water for injection, sodium hydroxide to adjust the pH.

##### What Fibro-Vein Injection looks like and the contents of the pack

Fibro-Vein is a clear, colourless solution.

Fibro-Vein Solution for Injection is available in 4 different strengths in the following pack sizes:

Concentration	Pack size
0.2%w/v	10X5ml vials
0.5%w.v	5X2ml ampoules
1.0% w/v	5X2ml ampoules
3%w/v	5X2ml ampoules
3%w/v	10X5ml vials

##### Marketing Authorisation Holder:

STD Pharmaceutical Products Ltd.  
Plough Lane  
Hereford  
HR4 0EL  
United Kingdom

##### Manufacturer:

STD Pharmaceutical Products Ltd.  
Plough Lane  
Hereford  
HR4 0EL  
United Kingdom

##### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Fibro-Vein Injection	PL 003981/0002

This is a service provided by the Royal National Institute of Blind People

Fibro-Vein 0.2%	PL 00398/0004	PA0246/001/007	POM
Fibro-Vein 0.5%	PL 00398/0002	PA0246/001/003	POM
Fibro-Vein 1%	PL 00398/0003	PA0246/001/004	POM
Fibro-Vein 3%(5ml)	PL 00398/5000	PA0246/001/006	POM
Fibro-Vein 3%(2ml)	PL00398/5000	PA0246/001/005A	POM

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