Package leaflet: Information for the user Fibrovein 0.2 %, 0.5 %, 1 % & 3 % Solution for Injection
sodium tetradecyl sulfate
Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
− Keep this leaflet. You may need toread it again.
− If you have any further questions, please ask your doctor or nurse.
− If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
What is in this leaflet
1. What Fibrovein is and what it is used for
2. What you need to know before you use Fibrovein
3. How to use Fibrovein
4. Possiblesideeffects
5. How to store Fibrovein
6. Contents of the pack and other information
1. WhatFibroveinisandwhatitisusedfor
The name of your medicine is Fibrovein, which contains the active ingredient sodium tetradecyl sulfate.
Different strengths of Fibrovein are used in the treatment of varicose veins, large, medium or minor venules and spider veins.
This injection belongs to a group of medicines called sclerosants. Sclerosants are chemical agents, when injected into the affected vein they cause 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.
Fibrovein is only for use in adults (including the elderly).
2. What you need to know before you use Fibrovein
Do not use Fibrovein if you:
• are allergic to sodium tetradecyl sulfate or to any of the other ingredients of this medicine (listed in section 6) or have an allergic condition
• cannot walk due to any reason or bedridden
• have risk of developing blood clots in your veins due to:
• inherited blood disorders such as thrombophilia
• having hormonal contraception or hormone replacement therapy. • being significantly overweight
• smoking
• immobility for long duration
• have had recent blood clots in superficial or deep veins or in the lungs
• have had recent surgery
• have twisted veins (varicose veins) caused by pelvic or abdominal tumours, unless the tumour has been removed

• have an uncontrolled ailment such as diabetes, excessive thyroid activity, asthma, blood abnormality, blood poisoning, or recent skin or breathing problems
• have swollen or a red area of the skin that feels hot or tender (cellulitis)
• have any kind of infection
• have evolving cancer
• have been told that you have problems with closing of valves in deep veins (valvular incompetence)
• have blockage in an artery
• have severe inflammation of veins in the legs (acute phlebitis)
• have a symptomatic hole in the heart (only if the sclerosant is used as a foam).
Warnings and precautions
Talk to your doctor before using Fibrovein if you:
• are allergic to any food or medicine or have any other allergies, 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
• have a history of blood clots in superficial or deep veins or in the lungs
• have an asymptomatic hole in the heart (if the sclerosant is used as a foam)

• have symptomatic or asymptomatic hole in the heart (if the sclerosant is used as a liquid)
• suffer from migraines
• have problems with the veins in your legs which is associated with a long-term condition that causes swelling in the body's tissues (Lymphoedema). Fibrovein may worsen local pain and inflammation for days or several weeks.
• have a history of pulmonary hypertension
• have a history of transient ischemic attack (TIA) stroke or serious cerebral event
• have been told that you have any disease of your arteries or veins (atherosclerosis)
• have severe inflammation and clotting of arteries and veins affecting the hands and feet (Buerger's disease)
• have any breathing difficulties that are controlled (asthma).

Fibrovein should be administered only by experienced healthcare professionals experienced in venous anatomy and familiar with proper injection technique. Before using this injection you may be tested to see if you have any problems with the closing of the valves in your veins.

Your doctor will ask you questions about your health and will inform you about the potential side effects of this procedure.

During treatment

Your doctor will monitor you during and after the sclerotherapy for signs of hypersensitivity (redness, itching, cough) or neurological symptoms (visual disorders, migraine, tingling or numbness).

He will ask you to come back for a follow up visit.

Children and adolescents

The safety and effectiveness of Fibrovein in children and adolescents have not been established.

Other medicines and Fibrovein

If you are taking hormonal contraception (e.g. 'the pill') or hormone replacement therapy (HRT) you may have a risk of developing blood clots in your veins (see 'Do not use Fibrovein if you'). You must tell your doctor or nurse.

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

Pregnancy and breast-feeding

You must tell the doctor if:

• you are pregnant or think you may be pregnant
• you are planning on becoming pregnant
• you are breast-feeding

There is no adequate information on the use of Fibrovein in pregnant women. Fibrovein should not be used during pregnancy unless clearly necessary. Your doctor will decide whether or not this treatment is appropriate for you.

It is not known whether Fibrovein is excreted in breast-milk. If you are breast-feeding, the doctor will decide whether Fibrovein should be used.

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.

Fibrovein contains sodium and potassium

This medicine contains:

• less than 1 mmol sodium (23 mg) per vial/ampoule, i.e. essentially 'sodium-free'.
• less than 1 mmol potassium (39 mg) per vial/ampoule, i.e. essentially 'potassium-free'.

3. How to use Fibrovein

You must not try to inject Fibrovein 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 the needles and it is to be injected slowly and with extreme care so that the blood content of these veins is expelled. The medicine may be manually mixed with air using two syringes and a connector to create a foam to help expel the blood in larger veins. In this case, it must be administered by a physician appropriately trained in the correct generation and administration of foam.

Your doctor should use ultrasound guidance in the treatment of non-visible varicose veins and for the administration of foam sclerosant.

Your doctor will decide on the areas to treat and the right dose for you. The recommended doses are as follows:
Adults and the elderly
• varies between 0.1 and 2 ml for each injection. A maximum of 10 ml of the three lower strength injections may be used, however no more than 4 ml is used when the strongest injection is used.
Due to the limited volume of sclerosant authorised, repeated sessions of sclerotherapy may be necessary.
After you have been treated with Fibrovein, 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.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
You may experience some serious side effects. Stop treatment with Fibrovein and immediately contact your doctor or go to the nearest hospital emergency department if you have any of the following:
Uncommon (may affect up to 1 in 100 people):
• Blood clots in deep veins (Deep vein thrombosis possibly due to underlying disease). Symptoms may include pain, swelling and tenderness in one of your legs (usually your calf), a heavy ache in the affected area, warm skin in the area of the clot or red skin particularly at the back of your leg below the knee.
Rare (may affect up to 1 in 1,000 people):
• Local tissue death of skin and more rarely of nerves. Symptoms include pain, skin discolouration (redness), swelling or fluid accumulation, blisters (may be filled with clear fluid or blood), skin turns dark red, purple, or black, abnormal sensation (tingling, prickling, burning), numbness or loss of sensation.
Very rare (may affect up to 1 in 10,000 people):
• A very severe form of allergic reaction (anaphylactic shock), which may cause breathing problems or a sudden drop in blood pressure making you feel faint or become unconscious. It is very rare but should be treated immediately, otherwise it may be fatal.
• Blockage of artery due to a clot which may cause:
o a stroke or an interruption in the blood supply to the brain or the eye (transient ischaemic attack). Symptoms may include weakness, numbness or paralysis in your face, arm or leg, typically on one side of your body, slurred or garbled speech or difficulty understanding others, blindness in one or both eyes or double vision.
o a blood clot in the lungs. Symptoms may include shortness of breath that may occur suddenly, a sudden, sharp chest pain that may become worse with deep breathing or coughing, rapid heart rate or rapid breathing.
To avoid this very rare serious event, this medicine must not be given to patients who have a risk of clots in veins and arteries (risk of thrombosis).
• Failure of blood circulation. Symptoms may include fatigue, blackouts, fainting, chest pain, shortness of breath, weakness, dizziness, vomiting and palpitations.
• Death of tissue following intra-arterial injection. Symptoms can vary depending on how much medicine was injected, where it was injected and how quickly medical attention was received. These can range from pain but no long-term damage, to loss of large areas of tissue including the foot, resulting in amputation.
Other side effects that may be experienced are:
Very common (may affect more than 1 in 10 people):
• Superficial inflammation of the vein
Common (may affect up to 1 in 10 people):
• Pain or burning (short term at the injection site)
• Skin discolouration
• Growth of very fine spider veins in the treated area (matting).

Uncommon (may affect up to 1 in 100 people):
• Local allergic and non-allergic skin reactions e.g. redness of skin, itchy skin, rash or swelling of the skin
• Visual disturbances. • Migraine
Rare (may affect up to 1 in 1,000 people):
• Coughing, shortness of breath, sensation of pressure/tightness in the chest
• Burning, tingling, prickling or itching of the skin
• Headache, feeling faint
• Confusion, dizziness, loss of consciousness.

Very rare (may affect up to 1 in 10,000 people):
• Fever, hot flushes, red itchy skin (hives)
• Nausea, vomiting, diarrhoea, feeling of swollen/thick tongue, dry mouth • Inflammation of blood vessels.
Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.
5. How to store Fibrovein
Keep this medicine out the sight and reach of children.
• This medicine does not require any special temperature storage conditions (Temperature Zone 1)
• Do not store above 25°C (For all other Temperature zones)
• Do not freeze.
• The injection should be stored in the outer carton to protect it from light.
• Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of the month.
For single use only. Once the container is opened, the contents should be used immediately. Any remaining product should be discarded.
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. Contents of the pack and other information What Fibrovein contains
The active ingredient is sodium tetradecyl sulfate.
For the 0.2 %:
Each ml of solution for injection contains 2 mg sodium tetradecyl sulfate. Each 5 ml vial contains 10 mg sodium tetradecyl sulfate.
For the 0.5 %:
Each ml of solution for injection contains 5 mg sodium tetradecyl sulfate. Each 2 ml ampoule contains 10 mg sodium tetradecyl sulfate.

For the 1 %:
Each ml of solution for injection contains 10 mg sodium tetradecyl sulfate. Each 2 ml ampoule contains 20 mg sodium tetradecyl sulfate.
For the 3 %:
Each ml of solution for injection contains 30 mg sodium tetradecyl sulfate. Each 2 ml ampoule contains 60 mg sodium tetradecyl sulfate.
Each 5 ml vial contains 150 mg sodium tetradecyl sulfate.
The other ingredients are: benzyl alcohol (20 mg/ml), disodium phosphate dodecahydrate, potassium dihydrogen phosphate, water for injections, sodium hydroxide (to adjust the pH). See section 2, ‘Fibrovein contains sodium and potassium’.
What Fibrovein looks like and the contents of the pack
This medicine is presented as a solution for injection in clear glass ampoules or vials. The solution is clear, colourless, sterile and free from visible particles.
For the 0.2 %: Pack size 2, 5 or 10 vials of 5 ml
For the 0.5 %: Pack size of 5 ampoules of 2 ml
For the 1 %: Pack size of 5 ampoules of 2 ml
For the 3 %: Pack size of 5 ampoules of 2 ml or 2, 5 or 10 vials of 5 ml
Not all pack sizes may be marketed.
Marketing Authorisation Holder
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Plough Lane, Hereford, HR4 0EL, United Kingdom
Manufacturer
STD Pharmaceutical Products Ltd.
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