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 to read 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

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.

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 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 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 a physician where national guidance permits. Fibrovein may be administered by appropriately qualified healthcare professionals, experienced in venous anatomy and familiar with proper injection technique under the supervision of a physician. 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 you 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, potassium and benzyl alcohol
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'.
- 40mg benzyl alcohol in each 2ml ampoule or 100mg benzyl alcohol in each 5ml vial, which is equivalent to 20mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant, breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

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:
    - 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.
    - 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 in 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 HPRA Pharmacovigilance Website: www.hpra.ie. 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.
- 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, 'Fibroveincontains 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
STD Pharmaceutical (Ireland) Ltd
Block 1, Blanchardstown Corporate Park,
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Blanchardstown
D15 AKK1
Dublin 15,
Ireland

Manufacturer
Medipha Sante
Les Fjords-Immeuble Oslo
19 Avenue de Norvege
91953 Courtaboeuf CEDEX
France

Or

Chemische Fabrik Kreussler & Co. GmbH
Rheingaustrasse 87-93
65203 Wiesbaden,
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

Bulgaria, Czech Republic, France, Germany, Ireland, Netherlands, Poland, Romania	Fibrovein
Austria, Spain	Veinfibro

This leaflet was last revised in:

05/2024

The following information is intended for healthcare professionals only:

Fibrovein 0.2 % Solution for Injection
Fibrovein0.5 % Solution for Injection
Fibrovein 1 % Solution for Injection
Fibrovein3 % Solution for Injection

Please refer to the Summary of Product Characteristics (SmPC) for further details of this product.

Posology and method of administration

Posology
Fibrovein is for intravenous use only. The strength of solution required depends on the size and degree of varicosity. Spider veins should only be treated with the 0.2%, reticular veins with 0.5%, the 1% solution will be found most useful for small to medium varicosities and the 3% solution for larger varicosities. The size of non-visible varicose veins should be measured under ultrasound.

The sclerosant should be administered intravenously in small aliquots at multiple sites along the vein to be treated. Fibrovein 0.2% & 0.5% must be administered as a liquid. Fibrovein 1% & 3% solutions can be administered as either as a liquid or as a sclerosant/air mixture (foam) as detailed in the table below. The objective is to achieve optimal destruction of the vessel wall with the minimum concentration of sclerosant necessary for a clinical result. If the concentration is too high necrosis or other adverse sequelae may occur.

Adults

Concentration	***Normal volume injected intravenously at suitable sites per session***		***Maximum total volume to be injected per session***	
	Liquid	*Foam**	*Liquid*	*Foam**
Fibrovein 0.2 % & 0.5 %	*0.1 to 1.0 ml*	*N/A*	*10 ml*	*N/A*
Fibrovein 1 %	*0.1 to 1.0 ml*	*0.5 to 2.0 ml*	*10 ml*	*16 ml*
Fibrovein 3 %	*0.5 to 2.0 ml*	*0.5 to 2.0 ml*	*4 ml*	*16 ml*

* volume is the *sum* of the liquid and air components

Where special caution is indicated it is recommended that a test dose of 0.25 to 0.5 ml Fibrovein should be given followed by observation of the patient for several hours before administration of a second or larger dose.

As the volume to be injected is limited per session, repeated sessions are usually needed (2 to 4 on average). To prevent a possible allergic reaction, it is recommended that a small test dose of Fibrovein should be given at the beginning of each session.

Fibrovein 1 % & 3 % Solution for Injection
When the sclerosant is administered as a foam
Fibrovein 1 % and 3 %, may be converted to a foam to be used for the treatment of larger veins. The foam must be prepared just before use and administered by a physician appropriately trained in the correct generation and administration of foam. It should ideally be administered under ultra sound guidance.

Fibrovein 0.2 % Solution for Injection
For spider veins 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.

Elderly population
No specific dose recommendations apply.

Paediatric population
The safety and efficacy of Fibrovein in children have not been established. No data are available.

Method of administration
Refer below for instructions for foam preparation. The Tessari method of preparation of the foam is described. Other techniques may be used (e.g. DSS, Easyfoam, Sterivein).

Strict aseptic technique must be maintained while handling Fibrovein. Fibrovein is a single-use parenteral product. Once the container is opened, use immediately and discard any unused portion.

Visually inspect for particulate matter before use. Solutions that contain particulate matter should not be used.

When the sclerosant is administered as a foam it should ideally be administered under ultrasound guidance. It must be administered by a physician appropriately trained in the correct generation and administration of the foam.

Incompatibilities
This medicinal product is not compatible with heparin.

In the absence of compatibility studies, this medicinal product should not be mixed with other medicinal products.

Special warnings and precautions
Fibrovein should only be administered by a physician, where national guidance permits. Fibrovein may be administered by appropriately qualified healthcare professionals experienced in venous anatomy and the diagnosis and treatment of conditions affecting the venous system and familiar with proper injection technique under the supervision of a physician.

Allergic reactions including anaphylaxis have been reported and the physician should be prepared to treat it appropriately. Emergency resuscitation equipment should be immediately available.
The patient should be treated in hospital as a precaution.

Severe adverse local effects, including tissue necrosis, may occur following extravasation; therefore, extreme care in intravenous needle placement and using the minimal effective volume at each injection site are important. The solution should be injected slowly.

Care should be taken not to inject the solution into an artery as this may lead to death of the tissue (tissue necrosis) and may result in loss of the limb.

Special care must be taken when injecting the foot and above and below the ankle (malleolar area) due to risk to one of the arteries. Compression must be applied when treating smaller veins as pigmentation may occur if blood is expelled at the injection site.

Preparation and handling
General guidelines:
The quality of foam depends on specific criteria:

1. The product concentration: Foam can only be prepared with concentrations of 1 to 3 % sodium tetradecyl sulfate.

2. The proportion of liquid to air: Usually, this ratio is 1 volume of liquid for 3 to 4 volumes of air.
3. Number of backwards and forwards passes: The physician should follow precisely the number of movements defined for each technique.
4. Macroscopic consistency of the foam: The quality of the foam should be checked outside of the syringe before administration. The foam should be homogeneous, soft and cohesive with no visible large bubbles. If large bubbles are visible, the foam should be thrown away and new foam prepared.
5. The total time of preparation of the foam: The preparation should take around 10 seconds from the first to the last backwards and forwards movement.
6. The maximum time between preparation and injection: The sclerosant foam must be used within sixty seconds of production. After sixty seconds, any remaining foam should be discarded. More foam should be prepared if required.

To Prepare the Foam (Tessari technique)
Strict aseptic technique must be maintained while manufacturing the foam.

To create the foam 1 ml of liquid sclerosant is drawn into a sterile syringe and 3 ml or 4 ml of sterile air is drawn into another sterile syringe. The air is drawn through a 0.2 μm filter to ensure it is sterile. The syringes are then connected using a sterile three way tap/valve (Fig. 1). The use of Luer lock syringes and eye protection are recommended when making the foam. The connection with the 3-way tap can fail under pressure with Luer slip syringes resulting in product being squirted out uncontrollably.

The sclerosant/air mixture is then forced back and forth from one syringe to the other through the 3-way valve at least 20 times to produce a smooth, consistent foam (Fig. 2&3).

The syringe containing the foam, is then removed and the vein is injected immediately (Fig. 4).

The sclerosant foam should be used within sixty seconds of production. After sixty seconds any remaining foam should be discarded. More foam should be prepared if required.

The quality of the foam should be checked before its administration. It should appear homogenous, white in colour with no large bubbles visible to the naked eye.


Figure 1


Figure 2

Figure 3

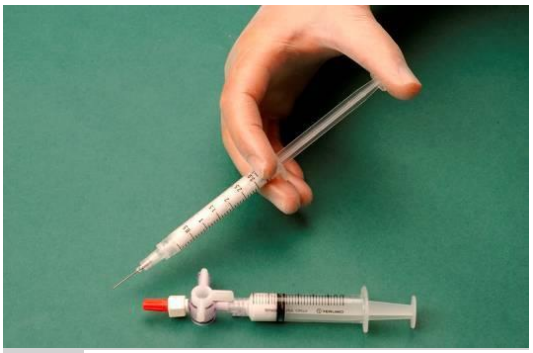

Figure 4

Excipients

This medicinal product 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’.
- 40mg benzyl alcohol in each 2ml ampoule or 100mg benzyl alcohol in each 5ml vial, which is equivalent to 20mg/ml. Benzyl alcohol may cause allergic reactions. May cause metabolic acidosis in patients who are pregnant, breast-feeding or have a liver or kidney disease.