

FIBROVEIN 3%, 1%, 0.5% and 0.2%

Sodium tetradecyl sulfate injection BP

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about FIBROVEIN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using FIBROVEIN against the benefits they expect it will have for you. It is important that you follow the instructions before and after treatment with FIBROVEIN.

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.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT FIBROVEIN IS USED FOR

FIBROVEIN contains sodium tetradecyl sulfate, which is one of the group of medicines known as sclerosants.

FIBROVEIN is only for use in adults (including the elderly) in a procedure called compression sclerotherapy; for the treatment of varicose veins.

BEFORE USING FIBROVEIN

FIBROVEIN should not be used if you have any of the following medical conditions. Before starting treatment, you must tell your doctor if you:

- are pregnant, trying to become pregnant or breast feeding
- have previously experienced a reaction to FIBROVEIN or any other product containing sodium tetradecyl sulfate
- are allergic (hypersensitive) to other medicines or to a variety of foods
- suffer from any of the following medical conditions:
 - asthma, lung disease, breathing problems or any allergic disease
 - tumours or any blood disorders
 - diabetes
 - difficulty walking
 - any skin problems
 - recent surgery
 - recent blood clots in superficial or deep veins or in the lungs
 - twisted veins (varicose veins) caused by pelvic or abdominal tumours, unless the tumour has been removed
 - any kind of infection
 - severe heart disease
 - excessive fluid accumulation in the lungs causing shortness of breath
 - blockage in an artery
 - problems with closing of valves in deep veins (valvular incompetence)
- are taking any of these medicines:
 - the oral contraceptive pill

- medicines for the treatment of blood clots (thrombosis)
- have severe inflammation of veins in the legs (acute phlebitis)
- have blood clots in your veins (thrombosis)
- have risk of developing blood clots in your veins due to:
 - inherited blood disorders such as thrombophilia
 - being significantly overweight
 - immobility for long duration
 - having hormonal contraception or hormone replacement therapy.
 - smoking

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.

During one treatment session, up to 10 sites of each limb may be injected with the lower strength solutions.

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

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.

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.

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.

HOW FIBROVEIN IS ADMINISTERED

Your doctor should use ultrasound guidance in the treatment of non visible varicose veins.

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

Dosage 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.

Children

FIBROVEIN is not intended for use for children.

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.

SIDE EFFECTS

Like all medicines, FIBROVEIN can cause side effects, although not everybody gets them.

Common (at least 1 in 100 but less than 1 in 10 patients):

- Pain or burning (short term at the injection site),
- Skin discolouration
- Superficial inflammation of the vein
- Growth of very fine spider veins in the treated area (matting)

Uncommon (at least 1 in 1,000 but less than 1 in 100 patients):

- Local allergic and non allergic skin reactions e.g. redness of skin, itchy skin, rash or swelling of the skin
- Blood clots in deep veins (Deep vein thrombosis possibly due to underlying disease)

Rare (at least 1 in 10,000 but less than 1 in 1,000 patients):

- Local tissue death of skin and more rarely of nerves
- Coughing, shortness of breath, sensation of pressure/tightness in the chest
- Burning, tingling, prickling or itching of the skin
- Headache, migraine, feeling faint
- Confusion, dizziness, loss of consciousness

Very rare (less than or 1 in 10,000 patients):

- Fever, hot flushes, asthma, red itchy skin (hives) or severe allergic reactions (anaphylactic shock)
- Nausea, vomiting, diarrhoea, feeling of swollen/thick tongue, dry mouth
- Visual disturbances
- Weakness, stroke like symptoms
- Blockage of artery due to a clot (stroke, transient ischemic attack, pulmonary embolism)
- Inflammation of blood vessels, failure of blood circulation
- Death of tissue following intra-arterial injection

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

The most serious side effects are:

- a very severe form of allergic reaction (anaphylactic shock). It is extremely rare but should be treated immediately, otherwise it may be fatal.
- a blood clot in the lungs. To avoid this very rare serious event, this product is contraindicated in patients who have a risk of clots in veins and arteries (risk of thrombosis).

IN CASE OF OVERDOSE

No cases of overdosage with FIBROVEIN have been reported.

AFTER USING FIBROVEIN

Storage

Keep out the reach and sight of children.

Store below 25°C, away from direct sunlight. The injection should be stored in the outer carton to protect it from light Do not freeze

FIBROVEIN should not be used after the expiry date given on the carton; 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.

PRODUCT DESCRIPTION

FIBROVEIN is a sterile clear and colourless solution for injection in clear glass ampoules or vials. It has a pH of 7.6,

Different strengths of FIBROVEIN are used in the treatment of varicose veins, large, medium or minor venules and spider veins.

FIBROVEIN comes in 4 strengths.

FIBROVEIN 3% 30 mg/1 mL, 10X5 mL glass vials AUST R 29772

FIBROVEIN 3% 60 mg/2mL, 5X 2 mL glass ampoules AUST R 29638

FIBROVEIN 1% 20 mg/2mL, 5X2 mL glass ampoules AUST R 73362

FIBROVEIN 0.5% 10 mg/2mL, 5X2 mL glass ampoules AUST R 73361

FIBROVEIN 0.2% 2 mg/1 mL, 10 X 5 mL glass vials AUST R 73360

Ingredients

FIBROVEIN 0.2% in 5 mL vial:
Each mL of solution for injection contains 2mg sodium tetradecyl sulfate.

FIBROVEIN 0.5% in 2 mL ampoule: Each 2 mL ampoule contains 10 mg sodium tetradecyl sulfate.

FIBROVEIN 1% in 2 mL ampoule: Each 2 mL ampoule contains 20mg sodium tetradecyl sulfate.

FIBROVEIN 3% in 2 mL ampoule: Each 2ml ampoule contains 60mg sodium tetradecyl sulfate.

FIBROVEIN 3% in 5 mL vial:
Each mL of solution for injection contains 30mg sodium tetradecyl sulfate.

The other ingredients are: benzyl alcohol (20 mg/ml or 2%), dibasic sodium phosphate, monobasic potassium phosphate, water for injections, sodium hydroxide (to adjust the pH).

SPONSOR

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Australian Registration Number

FIBROVEIN 3% sodium tetradecyl sulfate 30mg/2mL injection ampoule – AUST R 29638

FIBROVEIN 3% sodium tetradecyl sulfate 30mg/mL multidose injection vial – AUST R 29772

FIBROVEIN 0.2% sodium tetradecyl sulfate 2mg/mL injection vial – AUST R 73360

FIBROVEIN 0.5% sodium tetradecyl sulfate 10mg/2mL injection ampoule – AUST R 73361

FIBROVEIN 1.0% sodium tetradecyl sulfate 20mg/2ml injection ampoule – AUST R 73362

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