

Aethoxysklerol®

Generic name Lauromacrogol 400

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Aethoxysklerol.

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 having Aethoxysklerol against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Aethoxysklerol is used for

Aethoxysklerol is a sterile solution that is injected into varicose veins to cause closure of the affected vein and shrink the vessel(s).

How it works

Upon injection, Aethoxysklerol works by causing the lining of the blood vessel to break up and also stops the flow of blood through that vein. The affected area is then squeezed by application of a compression bandage which helps to complete closure of the varicose vein.

Before you are given Aethoxysklerol

When you must not be given it

Do not have Aethoxysklerol injected if you have an allergy to:

- Lauromacrogol 400 or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not have Aethoxysklerol injected if you have any of the following medical conditions:

- you are confined to bed or have difficulty in walking
- you have severe arterial disease
- blockage of blood vessels by blood clots or family history of blood clots or at least three of the following: you use hormonal contraceptives (e.g. the Pill) or hormone replacement medication, you are overweight, smoke or remain immobile for long periods
- swelling and redness along a vein which is extremely tender when touched
- acute infection of the skin (hot, tender and red skin, sometimes with fever and chills)
- any allergic disease
- acute infections
- uncontrolled systemic disease such as diabetes, overactive thyroid gland with increased

sweating, tremors and rapid heart rate, tuberculosis, asthma, tumours, severe venous abnormalities, blood poisoning (symptoms may include high fever, chills, headache, confusion, rapid breathing), a disease of the blood with a reduced number of red or white blood cells or platelets (symptoms may include tiredness, headaches, dizziness, being short of breath when exercising and looking pale; frequent infections such as fever, severe chills, sore throat or mouth ulcers; bleeding or bruising more easily than normal, nosebleeds), any lung or skin disease

- you have symptoms of a right-to-left shunt heart abnormality (only if doctor applies Aethoxysklerol as a microfoam)

If you are not sure whether you should have injections of Aethoxysklerol, talk to your doctor.

Before you are given it

Tell your doctor if have, or have had, any medical conditions, especially the following:

- a blood clotting disorder
- arterial disease with severe pain on walking (only if treatment of spider veins is intended)
- numbness or weakness of the arms and legs
- excessive accumulation of fluid in the leg
- blood vessels affected by disease, e.g. diabetes

- pain, swelling, redness and heat on skin in the area that is to be injected
- you have severe heart disease
- recent feverish temperature
- you are over 75 years old and in poor health
- if you know you have a right-to-left shunt heart abnormality, even if this causes no signs of disease/is not accompanied by any symptoms (only if doctor applies Aethoxysklerol as a microfoam)
- you have had visual or nerve problems after previous varicose vein treatment (only if doctor applied Aethoxysklerol as a microfoam)

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Aethoxysklerol is not recommended for use during pregnancy. If there is a need to consider injections during your pregnancy, your doctor will discuss the benefits and risks with you.

Tell your doctor if you are breast-feeding.

It is not known whether Aethoxysklerol passes into breast milk. If there is a need to consider injections whilst you are breast-feeding, your doctor will discuss the benefits and risks with you.

Tell your doctor if you have suffered from alcoholism.

Aethoxysklerol contains ethanol.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Aethoxysklerol may interfere with each other. These include:

- anaesthetics (medicines causing loss of feeling, especially pain)

These medicines may be affected by Aethoxysklerol or may affect how well it works. (You may need different amounts of these medicines, or you may need to take different medicines.) Your doctor or pharmacist will advise you and decide whether or not to give the medicine.

How and when Aethoxysklerol is given

Aethoxysklerol is given by injection into the varicose vein. It should always be injected by a doctor who has been trained in the proper techniques for injecting varicose veins. The actual dose and selection of the Aethoxysklerol concentration to be used will depend on the size of the varicose vein to be treated. Before injection, the leg must be lifted to a horizontal position or preferably lifted 30-45° above the horizontal.

Once the injection site has been covered, a firm compression bandage or elastic stocking will be applied. Immediately after fitting of the bandage, you will be asked to walk for 30 minutes in the surgery. The bandage or stocking should be worn for several days or weeks, depending on the size of the varicose veins treated. For very small vessels a period of 2-7 days is usually sufficient.

For larger varicose veins, longer compression-treatment with bandages is recommended. The bandage may need to be worn for 4-6 weeks.

Several repeat treatments at intervals of 1-2 weeks may be necessary, depending on the severity and extent of the varicose veins.

The success of treatment depends heavily on the thorough and careful follow-up compression treatment. Please follow the advice of your doctor.

How much is given

Your doctor will decide on the dose depending on the size and type of vein to be treated.

If you are given too much

It is unlikely that you will be given too much medicine. Extensive varicose veins will always be treated in several sessions. If there is any likelihood of a hypersensitivity (allergic-type) reaction, only one injection will be given. Depending on the outcome and size of the area to be treated, several injections may be given at subsequent treatment sessions.

After Aethoxysklerol injection

Things you must do

Keep a record of your injections.

Keep follow-up appointments with your doctor or clinic.

It is important to have your follow-up injections of Aethoxysklerol at the appropriate times to help make sure the treatment is successful.

Things to be careful of

Make sure that the bandage does not slip down, if you suspect that the compression bandage is not doing its job see your doctor.

Make sure you tell your doctor if you think you may be having an allergic reaction to Aethoxysklerol. Your doctor will take appropriate measures and will need to know what other medicines you are currently taking.

Side effects

Tell your doctor as soon as possible if you do not feel well after having an injection of Aethoxysklerol.

Aethoxysklerol may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- pinkish, itchy swellings on the skin, also called hives or nettle rash, redness of the skin or any other skin reaction
- asthma (asthmatic attack)
- headache or migraine
- tingling or numbness of the hands, feet or mouth
- feeling of confusion or dizziness
- visual disturbances
- fast, slow or irregular heart beats, also called palpitations
- development of new tiny blood vessels
- swelling and redness along a vein which is extremely tender when touched
- fainting
- inflammation of blood vessels, often with skin rash
- difficulty in breathing or sensation of pressure in the chest
- coughing
- taste disturbance or loss of taste
- nausea or vomiting
- darker areas of skin or bruising
- excessive growth of normal hair at the injection site
- pain in the limb
- pain or blood clot formation at the injection site
- local tissue death
- appearance of lumps or swelling at the injection site
- fever, sensation of heat

- unusual weakness or generally feeling unwell
- muscular weakness on one side of the body
- change of blood pressure
- nerve injury, often with numbness or tingling
- unusual difficulty with speaking, thinking or muscle coordination

Some of the side effects listed above are more common but most of them are rare or very rare. They are usually mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, difficulty in swallowing, shortness of breath, wheezing or trouble breathing.
- stroke
- loss of consciousness
- heart attack
- sudden chest pain, a very rapid or irregular heartbeat, or shortness of breath after a stressful situation (also called stress cardiomyopathy)
- blood clot, usually in a leg, which causes pain, swelling or redness
- blockage of lung artery which causes chest pain and breathlessness
- collapse due to very low blood pressure

These may be serious side effects.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Most of the serious side effects are very rare.

Other side effects not listed above may occur in some patients.

Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storing Aethoxysklerol

Aethoxysklerol is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Aethoxysklerol:

- **Keep it where children cannot reach it.**
- **Keep Aethoxysklerol in the original pack until it is time for it to be given.**
- **Keep it at room temperature (below 30°C), do not expose to excessive heat.**

Product description

What it looks like

A clear, colourless to faintly yellowish-green solution, free of particles.

Ingredients

Active ingredient: lauromacrogol 400

Other ingredients: ethanol, dibasic sodium phosphate dihydrate, monobasic potassium phosphate, water for injections.

Aethoxysklerol does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

AGS Pharma Pty Ltd
PO Box 738
Pennant Hills NSW 1715

Manufacturer/ Distributor

Aethoxysklerol is made in Germany by:

Chemische Fabrik Kreussler & Co. GmbH

Rheingastrasse 87-93
65203 Wiesbaden

and distributed in Australia by:

Getz Healthcare Pty Limited
5 Orion Road
Lane Cove NSW 2066
Phone: 1300 886 385

Aethoxysklerol 0.5% (10 mg/ 2mL
lauromacrogol 400) AUST R 79118

Aethoxysklerol 1% (20 mg/ 2mL
lauromacrogol 400) AUST R 79119

Aethoxysklerol 3% (60 mg/ 2 mL
lauromacrogol 400) AUST R 79121

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