

Aethoxysklerol®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why I am given Aethoxysklerol?

Aethoxysklerol contains the active ingredient lauromacrogol 400. Aethoxysklerol is used to treat varicose veins.

For more information, see Section [1. Why I am given Aethoxysklerol?](#) in the full CMI.

2. What should I know before I am given Aethoxysklerol?

Do not use if you have ever had an allergic reaction to Aethoxysklerol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Aethoxysklerol?](#) in the full CMI.

3. What if I am taking other medicines?

Aethoxysklerol may interfere with some medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Aethoxysklerol given?

- Your doctor injects Aethoxysklerol into the varicose vein and selects the appropriate dose.
- After injection, a firm compression bandage or elastic stocking will be applied.

More information can be found in Section [4. How is Aethoxysklerol given?](#) in the full CMI.

5. After Aethoxysklerol injection

Things you should do	<ul style="list-style-type: none">• Keep a record of your injections.• Keep follow-up appointments with your doctor or clinic.
Things to be careful of	<ul style="list-style-type: none">• Make sure you tell your doctor if you think you may be having an allergic reaction to Aethoxysklerol.• Make sure the bandage does not slip down.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in the original pack, at room temperature (below 30°C), and do not expose to excessive heat. Keep it where young children cannot reach it.

For more information, see Section [5. After Aethoxysklerol injection](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects after treatment with Aethoxysklerol, most of them are minor and temporary. However, some side effects may need medical attention. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of the following serious side effects:

- 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.
- blockage of lung artery which causes chest pain and breathlessness.
- stroke, with symptoms including an inability to move or feel on one side of the body, problems with understanding or speaking, longer lasting loss of vision.
- heart attack.
- sudden chest pain, a very rapid or irregular heartbeat, or shortness of breath after a stressful situation (also called stress cardiomyopathy).

Most of the serious side effects are very rare.

The most commonly reported side effects are temporary in most cases and include pain or blood clot formation at the injection site and skin discolouration after treatment.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Aethoxysklerol[®]

Active ingredient: *lauromacrogol 400*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Aethoxysklerol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Aethoxysklerol.**

Where to find information in this leaflet:

- [1. Why I am given Aethoxysklerol?](#)
- [2. What should I know before I am given Aethoxysklerol?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Aethoxysklerol given?](#)
- [5. After Aethoxysklerol injection](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why I am given Aethoxysklerol?

Aethoxysklerol contains the active ingredient **lauromacrogol 400**. Aethoxysklerol is a medicine for treatment of varicose veins.

Aethoxysklerol is a sterile solution that is injected into varicose veins to cause them to close and shrink.

Aethoxysklerol works by causing the lining of the blood vessel to break up and stops the flow of blood through that vein. The affected area is then squeezed by application of a compression bandage or stocking which helps to completely close the varicose vein.

2. What should I know before I am given Aethoxysklerol?

Warnings

Do not have Aethoxysklerol injected if:

- you are allergic to lauromacrogol 400, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are confined to bed or have difficulty in walking.
- you have severe disease of the arteries in which blood vessel walls thicken and harden due to cholesterol deposits.
- you have 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.

- you have swelling and redness along a vein which is extremely tender when touched.
- you have been told by a doctor your veins have severe abnormalities.
- you have acute infection of the skin (hot, tender, and red skin, sometimes with fever and chills).
- you have any allergic disease.
- you have acute infections.
- you have uncontrolled systemic disease such as diabetes, overactive thyroid gland with increased sweating, tremors and rapid heart rate, tuberculosis, asthma, tumours, 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).

Check with your doctor if you:

- have a blood clotting disorder.
- have arterial disease with severe pain on walking (only if treatment of spider veins is intended).
- have numbness or weakness of the arms and legs.
- have excessive accumulation of fluid in the leg.
- have blood vessels affected by disease, e.g. diabetes.
- have pain, swelling, redness and heat on skin in the area that is to be injected.
- have severe heart disease.
- have had a fever recently.
- are over 75 years old and in poor health.
- know you have a right-to-left shunt heart abnormality, even if you have no symptoms (only if doctor applies Aethoxysklerol as a microfoam).
- have had visual or nerve problems after previous varicose vein treatment (only if doctor applied Aethoxysklerol as a microfoam).
- have suffered from alcoholism. Aethoxysklerol contains ethanol.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

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

Aethoxysklerol may increase the effect of the following medicines:

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Aethoxysklerol.

4. How is Aethoxysklerol given?

Aethoxysklerol is injected 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.

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.

When Aethoxysklerol is given

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

If you are given too much Aethoxysklerol

It is unlikely that you will be given too much Aethoxysklerol. 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.

5. After Aethoxysklerol injection

Things you should 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.

Looking after your medicine

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

- 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.

Keep it where young children cannot reach it.

Aethoxysklerol should not be given if the expiry date printed on the carton has passed.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects after treatment with Aethoxysklerol, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Nervous system-related: <ul style="list-style-type: none">• headache or migraine• tingling or numbness of the hands, feet or mouth	Speak to your doctor if you have any of these less

<ul style="list-style-type: none"> feeling of confusion or dizziness unusual difficulty with speaking, thinking or muscle coordination muscular weakness on one side of the body <p>Eye-related:</p> <ul style="list-style-type: none"> changes in your vision <p>Heart-related:</p> <ul style="list-style-type: none"> fast, slow or irregular heart beats, also called palpitations change in blood pressure <p>Blood vessel-related:</p> <ul style="list-style-type: none"> development of new tiny blood vessels swelling and redness along a vein which is extremely tender when touched inflammation of blood vessels, often with skin rash <p>Breathing-related:</p> <ul style="list-style-type: none"> difficulty in breathing or sensation of pressure in the chest coughing asthma <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> taste disturbance or loss of taste nausea or vomiting <p>Skin-related:</p> <ul style="list-style-type: none"> pinkish, itchy swellings on the skin (hives), redness of the skin or any other skin reaction darker areas of skin or bruising excessive growth of normal hair at the injection site <p>Muscle-related:</p> <ul style="list-style-type: none"> pain in the limb <p>Injection-site related:</p> <ul style="list-style-type: none"> pain or blood clot formation at the injection site local tissue death appearance of lumps or swelling at the injection site nerve injury, often with numbness or tingling <p>General body-related:</p> <ul style="list-style-type: none"> fever, sensation of heat unusual weakness or generally feeling unwell 	<p>serious side effects and they worry you.</p> <p>Some of these side effects are more common but most of them are rare or very rare. They are usually mild and short-lived.</p>
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Serious side effects

Serious side effects	What to do
<p>Allergy-related:</p> <ul style="list-style-type: none"> 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. <p>Nervous system-related:</p> <ul style="list-style-type: none"> stroke, with symptoms including an inability to move or feel on one side of the body, problems with understanding or speaking, longer lasting loss of vision loss of consciousness <p>Heart-related:</p> <ul style="list-style-type: none"> heart attack sudden chest pain, a very rapid or irregular heartbeat, or shortness of breath after a stressful situation (also called stress cardiomyopathy) <p>Blood-vessel related:</p> <ul style="list-style-type: none"> 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>Most of the serious side effects are very rare.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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

You may not experience any of them.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Aethoxysklerol contains

Active ingredient (main ingredient)	lauromacrogol 400
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• ethanol• dibasic sodium phosphate dihydrate• monobasic potassium phosphate• water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What Aethoxysklerol looks like

Aethoxysklerol is a clear, colourless to faintly yellowish-green solution, free of particles. Supplied in packs of 5 ampoules.

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

Who distributes Aethoxysklerol

Sponsor

Accelagen Pty Ltd
Suite 2.02
785 Toorak Road,
Hawthorn East VIC 3123

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
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