Package leaflet

Aethoxysklerol® 1%

Active substance: lauromacrogol 400 (polidocanol)
Solution for intravenous injection, used for the obliteration of varicose veins

Dear Patient,
Aethoxysklerol 1% is administered by a doctor. Nevertheless, please read the following leaflet carefully before treatment, because it contains important information about what you should observe during use of this medicine.

– Keep this leaflet. You may need to read it again.
– If you have any further questions, ask your doctor or your pharmacist.
– If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Aethoxysklerol 1% is and what it is used for

Different concentrations of Aethoxysklerol are required, depending on the size of the varicose veins (varices) to be obliterated (sclerosed).
Aethoxysklerol 1% is used as a liquid for sclerotherapy of central veins of spider veins, web-like varicose veins (reticular varices) and small varicose veins (varices) and as a foam for sclerotherapy of small varicose veins.
When several concentrations are listed as treatment, the vein diameter and the patient's individual situation should be considered. In case of doubt, the lower concentration should be chosen.

2. Before you use Aethoxysklerol 1%

Do not use Aethoxysklerol 1%

– in patients with known allergy to lauromacrogol 400 (polidocanol) or any of the other ingredients of Aethoxysklerol
– in patients with acute severe disease (especially if untreated).
– in bedridden patients or patients who are unable to walk
– in patients with severe, arterial blood flow problems (arterial occlusive disease Fontaine stage III and IV)
– in patients with a blood vessel blockage due to a local or detached blood clot (thromboembolic diseases)
– in patients at high risk of blood vessel blockage (thrombosis), e.g. patients born with a tendency for blood clots or with several risk factors, such as the use of hormonal contraceptives (e.g. the Pill) or hormone replacement therapy, being overweight, smoking, extended periods of immobility, etc.

Also applicable to foam sclerotherapy:
– in patients with symptoms caused by a known hole in the atrial septum of the heart (known symptomatic patent foramen ovale).

Take special care with Aethoxysklerol 1%
if the following conditions or diseases are present:
– feverish states
– attacks of breathlessness (bronchial asthma) or marked predisposition to allergies
– very poor general state of health
– spider veins: arterial blood flow problems (occlusive disease Fontaine stage II)
– swollen legs with accumulation of watery fluid (leg oedema), if this cannot be influenced by compression
– inflammatory skin disease in the treatment area
– symptoms of a blockage in the small blood vessels and capillaries e.g. due to diabetes (microangiopathy) or sensory impairment (neuropathy)
– reduced mobility.

Also applicable to foam sclerotherapy:
– a known hole in the atrial septum of the heart, even if this causes no signs of disease / is not accompanied by any symptoms (known asymptomatic patent foramen ovale)
– history of impaired eyesight, mood disorders or nerve dysfunction (visual, psychiatric or neurological symptoms) after previous foam sclerotherapy.

Using other medicines
Please tell your doctor or pharmacist if you are taking or using, or have recently taken or used, any other medicines, including medicines obtained without a prescription.
The effect of the following medicines or groups of medicines may be influenced if used at the same time as treatment with Aethoxysklerol 1%.
The active substance lauromacrogol 400 (polidocanol) is also a local painkiller (local anaesthetic). Therefore, when given at the same time as other anaesthetics, there is a risk of enhancing the effect of the anaesthetics on the cardiovascular system.

Pregnancy and breast-feeding
Pregnancy
If you are pregnant, your attending doctor must not administer Aethoxysklerol 1% to you unless it is absolutely necessary, as there is not enough experience with the use of Aethoxysklerol 1% in pregnant women. Studies in animals did not produce any evidence of harmful effects on the embryo or foetus.
Breast-feeding
If sclerotherapy is required during breast-feeding, it is advisable to suspend breast-feeding for 2-3 days, as studies on the passage of lauromacrogol 400 (polidocanol) into breast milk have not been performed in humans.

Driving and using machines
There are no known negative effects of Aethoxysklerol on the ability to drive and use machines.

Important notes on use
Sclerosants must never be injected into an artery (intra-arterially) because this can cause extensive tissue death (necrosis), which may require amputation. A vascular surgeon must be called in immediately if any such incidents occur.
For all sclerosants, there must be a strict indication for use in the facial area, as pressure reversal in the arteries may occur in this region, which may lead to permanent visual impairment (blindness).
In certain body regions, such as in the foot or ankle region, the risk of inadvertent injection into an artery may be increased. In such areas, only small amounts should be used with particular care during treatment.
The recommended mean volume of sclerosing foam per session is 2 to 8 ml; the maximum volume of sclerosing foam per session (for one or more injections) is 10 ml.
When treating dysfunctional truncal (main) veins, the foam injection is given at a minimum distance of 8 to 10 cm from the sapheno-femoral junction. If ultrasound monitoring reveals a large amount of foam in the deep vein system, muscle activation should be performed by the patient, e.g. bending and stretching the foot at the ankle joint.

Important warnings about some of the ingredients of Aethoxysklerol 1%
This medicinal product contains 5 vol % ethanol (alcohol), i.e. up to 84 mg per ampoule, equivalent to 2 ml beer, 0.8 ml wine per ampoule. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.
This medicinal product contains potassium, less than 1 mmol (39 mg) per ampoule, i.e. essentially 'potassium-free'.
This medicinal product contains sodium, less than 1 mmol (23 mg) per ampoule, i.e. essentially 'sodium-free'.

3. How to use Aethoxysklerol 1%

Dosage instructions
Generally, the dose of 2 mg lauromacrogol 400 (polidocanol) per kg body weight and day should not be exceeded (for a patient weighing 70 kg, this means a daily dose of up to 14 ml Aethoxysklerol 1%).
Aethoxysklerol may be used for foam sclerotherapy. Your doctor has access to more detailed information in the Summary of Product Characteristics for healthcare professionals. When administering as standardised sclerosing foam, the total dose of 10 ml foam per session and day – irrespective of body weight – should not be exceeded.
In the initial treatment, patients prone to hypersensitivity reactions should be given no more than one injection. Depending on the response, several injections may be given in subsequent treatment sessions, provided that the maximum dose is not exceeded.
Depending on the size of the area to be sclerosed, 0.1-0.3 ml Aethoxysklerol 1% is given as a liquid into the veins (intravascularly).
When using Aethoxysklerol as sclerosing foam, e.g. for the treatment of collateral varices, up to 4 ml (maximum 6 ml) is injected per injection. For veins connecting to the deep vein system, up to 2 ml (maximum 4 ml) is injected per injection. The total daily dose must not be exceeded.

Concentrations of sclerosing foam depending on the indication

Examples of indications	Aethoxysklerol	
	1%	3%
Vena saphena magna (great saphenous vein)		+
Vena saphena parva (small saphenous vein)		+
Collateral varices	+	
Perforating veins (connecting to the deep vein system)	+	

Note: The concentrations stated refer to liquid Aethoxysklerol for the preparation of sclerosing foam

Method of administration
Usually, the injections should only be carried out in a leg placed horizontally or elevated to approximately 30-45° above the horizontal.

Injections of Aethoxysklerol 1% must be given into the blood vessel (intravascularly).
Extra fine needles (e.g. insulin needles) and smooth-moving syringes are used. Using the narrowest puncture angle possible, the needle is inserted until its tip is securely located within the blood vessel.
When performing foam sclerotherapy, ultrasound imaging (preferably with duplex) should be used to monitor direct puncture and injection into non-visible main (truncal) veins, veins connecting to the deep vein system (perforating veins) and varicose veins (varices) located in the groin or hollow of the knee. When treating other non-visible varicose veins (varices), guidance of the puncture and injection by means of ultrasound is recommended.
When using sclerosing foam, the needle must be no smaller than 25G.

Compression treatment after injection of liquid Aethoxysklerol

Once the injection site has been covered, a tight compression bandage or compression stocking must be applied. Thereafter, the patient should walk for 30 minutes, preferably within reach of the practice.

Compression treatment after injection of Aethoxysklerol sclerosing foam

Once the injection site has been covered, the patient's leg is immobilised for 2-5 minutes. Valsalva's manoeuvre and muscle activation should be avoided in the patient, as should immediate compression in the injection site area. Compression is applied after approximately 10 minutes when treating the great and small saphenous vein (vena saphena magna / vena saphena parva) and after approximately 5 minutes when treating collateral varicose veins, recurrent varicose veins (occurring again after previous varicose vein treatment) or veins connecting to the deep vein system.

Duration of compression

Compression should be applied for 5-7 days. For extensive varicose veins, prolonged compression treatment with short-traction bandages is recommended.
To ensure that the bandage does not slip, especially on the thigh and conical limbs, it is recommended that a foam bandage support is applied under the actual compression bandage.
The success of sclerotherapy is largely dependent on thorough and careful follow-up compression treatment.

Frequency and duration of use

Depending on the extent of the varicose veins, several courses of repeated treatment may be required.

If more is used than recommended

An overdose can cause local tissue destruction, particularly if injected into the surrounding tissue.

If you forget to use Aethoxysklerol 1%

Not applicable.

Other questions

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

In this section we inform you about adverse reactions that have been reported in connection with the world-wide use of the active substance. Sometimes reactions have been troublesome but fortunately mostly were of temporary nature only. Because these reactions are often reported spontaneously from a population of uncertain size and without a control group, it is not possible to estimate their frequency exactly or to establish a definite causal relationship to drug exposure in each case. Nevertheless a reasonable assumption can be made based upon the long-term experience.
Local adverse reactions (e.g. tissue destruction), especially of the skin and underlying tissue (and, in rare cases, of the nerves) have been observed when obliterating (sclerosing) varicose veins. These occurred after inadvertent injection into the surrounding tissue. The risk increases with increasing Aethoxysklerol concentrations and amounts. Otherwise, the following adverse reactions have been observed with varying frequency:

very common	more than 1 in 10 patients treated
common	less than 1 in 10, but more than 1 in 100 patients treated
uncommon	less than 1 in 100, but more than 1 in 1,000 patients treated
rare	less than 1 in 1,000, but more than 1 in 10,000 patients treated
very rare	less than 1 in 10,000 patients treated, including isolated cases

Very common
– Not applicable.

Common
– occurrence of blood vessels in the area of sclerotisation that were not visible prior to treatment (neovascularisation), bruising (haematoma)
– discolouration of the skin (hyperpigmentation), bleeding into the skin (ecchymosis)
– pain at the injection site (short-term), blood clot formation (thrombosis) at the injection site (local blood clot formation within the blood vessel)

Uncommon
– superficial inflammation of the vein (superficial thrombophlebitis), vein inflammation (phlebitis)
– allergic inflammation of the skin (allergic dermatitis), hives (urticaria), skin reactions, reddening (erythema)
– local tissue destruction (necrosis), tissue hardening (induration), swelling
– nerve injury

Rare
– deep vein thrombosis (possibly due to the underlying disease)
– pain in one limb

Very rare
– allergic shock (anaphylactic shock; symptoms include sudden breathing difficulties, dizziness, drop in blood pressure), angioedema (symptoms are sudden swelling, especially in the face, e.g. of the eyelids, lips or larynx), generalised hives (urticaria), asthma (asthma attack)
– stroke (apoplectic stroke), headache, migraine (rare with the sclerosing foam), local sensory disturbances (paraesthesia), loss of consciousness, confusion, dizziness, central language disorder (aphasia), coordination disorder (ataxia), muscular weakness on one side of the body (hemiparesis), partial loss of sensation in the mouth (hypoesthesia oral)
– worsening eyesight (transient visual disturbances (rare with the sclerosing foam))
– cardiac arrest, broken heart syndrome (stress cardiomyopathy), palpitations, heart rate abnormal
– lung embolism, cardiovascular problems (vasovagal syncope), circulatory collapse, inflammation of the blood vessel wall (vasculitis)
– breathing problems (dyspnoea), chest discomfort (sensation of pressure in the chest), cough
– altered taste, nausea, vomiting
– increased body hair (hypertrichosis) in the area of sclerotisation
– fever, hot flushes, feeling weak (asthenia), feeling unwell
– changes in blood pressure (abnormal blood pressure)

Measures to treat side effects

Allergic shock (anaphylactic reaction) is very rare but potentially life-threatening. The attending physician should be prepared for emergency measures and have a suitable emergency kit at his/her disposal.

Unknown side effects

If you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. How to store Aethoxysklerol 1%

Keep out of the reach and sight of children.

Note on expiry date

The expiry date of this pack is printed on the container and cardboard box. Please do not use this pack after this date.

Special precautions for storage

Do not store above 30°C.

Shelf life after first opening

This medicinal product is intended for single use. Discard any remaining amounts.

Warning on visible quality defects

No warnings are required.

6. Further information

Composition

1 ampoule with 2 ml Aethoxysklerol 1% contains:

Active substance:

20 mg lauromacrogol 400 (polidocanol)

Other ingredients:

Ethanol 96%, potassium dihydrogen phosphate, disodium phosphate dihydrate, water for injections

What the medicine looks like and contents of the pack

Aethoxysklerol 1% is a clear solution available in packs of 5 glass ampoules, each containing 2 ml.

Marketing Authorisation Holder and Manufacturer

Chemische Fabrik Kreussler & Co. GmbH
Rheingaustraße 87-93
65203 Wiesbaden, Germany
Phone: +49 611 9271-0
Fax: +49 611 9271-111
www.kreussler.com
E-mail: info@kreussler.com

Properties
In addition to its sclerosing properties, lauromacrogol 400 (polidocanol) also has a local painkilling (anaesthetic) effect.
With correct treatment and after-care, Aethoxysklerol 1% is well tolerated.
Medicinal product subject to medical prescription

Revision date: May 2018
Revision No.: Mo4

kreussler PHARMA

10 CM 4136 b 19.01