Abbreviated Prescribing Information

Refer to Aethoxysklerol SmPC before prescribing.

Name: Aethoxysklerol 2.5 mg/ml solution for injection, 5 mg/ml solution for injection, 10mg/ml solution for injection, 20 mg/ ml solution for injection and 30 mg/ml solution for injection.

Presentation: Aethoxysklerol is a sterile clear, colourless to very faintly greenish yellow solution for injection presented in a 2ml glass ampoule containing lauromacrogol 400 also known as polidocanol, 42 mg ethanol per ml, 0.310 mg sodium per ml, and 0.124 mg potassium per ml, of pH 7.0 – 8.0.

Indications: Aethoxysklerol is indicated for sclerotherapy of varicose veins of the lower extremities.

Dosage and Administration: Different concentrations of Aethoxysklerol are required, depending on the type and size of the varicose veins to be treated. Aethoxysklerol is for intravenous use only. If several concentrations are stated for a certain type of vein per the SmPC, the diameter of the vein and the patient's individual situation should be considered. In case of doubt the lower concentration should be chosen. Depending on the degree and extent of the varicose veins, several treatments may be required. Telangiectasias (Spider veins) should be treated with 2.5 mg/ml or 5 mg/ml; central veins of telangiectasis with 2.5 mg/ml, 5 mg/ml or 10mg/ml, reticular veins and small varicose veins with 10 mg/ml; medium varicose veins with 20 mg/ ml or 30 mg/ml; large varicose veins with 30 mg/ml. The sclerosant should be administered in small aliquots intravenously along the affected vein as a liquid. Alternatively as liquid or microfoam for treatment of small, medium and large varicose veins. When applying as a sclerosing microfoam, it is recommended not to exceed the total dose of 10 ml microfoam (the sum of liquid and air components) per session and day – irrespective of the patient's body weight and concentration of lauromacrogol 400.

Sclerotherapy of varicose veins: Generally, the dose of 2 mg lauromacrogol 400 per kg body weight per day should not be exceeded.

Sclerotherapy of telangiectasias: Depending on the size of the area to be treated, per puncture 0.1-0.2 ml Aethoxysklerol 2.5mg/ml or 5 mg/ml are injected intravenously.

Sclerotherapy of central veins of telangiectasias: Depending on the size of the area to be treated, per puncture 0.1-0.2 ml Aethoxysklerol 2.5 mg/ml, 5 mg/ml or 10 mg/ml are injected intravenously.

Sclerotherapy of reticular veins: Depending on the size of the varicose vein to be treated, per puncture 0.1- 0.3 ml Aethoxysklerol 10 mg/ml are injected intravenously.

Sclerotherapy of small varicose veins: Depending on the size of the varicose vein to be treated, per puncture 0.1-0.3 ml liquid Aethoxysklerol 10 mg/ml are injected intravenously. When using Aethoxysklerol 10 mg/ml microfoam, e.g. for the treatment of tributary varicose veins (collateral varices), up to 4-6 ml are injected per puncture. When treating perforating veins with microfoam up to 2-4 ml are injected per puncture.

Sclerotherapy of medium-sized varicose veins: Depending on the diameter of the varicose veins to be treated, Aethoxysklerol 20 mg/ml or 30 mg/ml is used. Depending on the length of the segment to be treated, several injections with up to 2 ml of liquid Aethoxysklerol 20mg/ml or 30 mg/ml per injection may be administered, without exceeding the maximum daily dose. When using Aethoxysklerol 20 mg/ml microfoam, e.g., for the treatment of perforating or tributary varicose veins, up to 2 ml microfoam are injected per puncture. When using Aethoxysklerol 20 mg/ml or 30 mg/ml microfoam, e.g., for the treatment of the saphenous veins, up to 4 ml are injected per puncture for the small saphenous veins and up to 6 ml for the great saphenous veins.

Sclerotherapy of large varicose veins: Depending on the length of the segment to be treated, several injections with up to 2 ml of liquid Aethoxysklerol 30 mg/ml per injection may be administered, without exceeding the maximum daily dose. When using Aethoxysklerol 30 mg/ml microfoam, e.g., for the treatment of the saphenous veins, up to 4 ml are injected per puncture for the small saphenous veins and up to 6 ml for the great saphenous veins.

Elderly population: No specific dose recommendations apply.

Paediatric population: No paediatric indication.

Hepatic impairment/Renal impairment: No pharmacokinetic studies have been performed in patients with hepatic or renal impairment. The use of sclerotherapy should be cautious and assessed in patients with moderate hepatic or renal impairment, in whom the treatment benefit clearly outweighs the risk. Aethoxysklerol is not recommended for use in patients with severe hepatic or renal impairment.

Contraindications: Known hypersensitivity to lauromacrogol 400 or any of the excipients. Uncontrolled systemic diseases (such as diabetes melitus, toxic hyperthyroidism, tuberculosis, asthma, neoplasm, systemic infections, blood dyscrasias, acute respiratory or skin diseases). Immobility, inability to walk due to any cause, i.e., the patient is immobile. Severe arterial occlusive disease (Fontaine stages III and IV) Thromboembolic diseases; High risk of thrombosis (e.g., known hereditary thrombophilia or patients with multiple risk factors such as use of hormonal contraceptives or hormone replacement therapy, obesity, smoking, and extended periods of immobility). In addition, the following contraindication applies to Microfoam sclerotherapy: Known symptomatic right-to- left shunt (e.g. symptomatic patent foramen ovale (PFO)).

Special Warnings and Precautions: Aethoxysklerol should only be administered by healthcare professionals experienced in sclerotherapy and the required preparation techniques. Sclerotherapy of varicose veins should be used with caution in patients with asymptomatic but known PFO, visual or neurological symptoms after previous microfoam treatment, fever, bronchial asthma or allergies, arterial occlusive disease, leg oedema, Inflammatory skin disease, patients with symptomatic microangiopathy or neuropathy, and patients using anticoagulation medication. A suitable emergency kit should be available in case of anaphylactic reaction. Before treatment, the healthcare professional should investigate the patient's risk factors and inform them about the risks of the technique. A thorough pre-procedure evaluation for valvular competency should be carried out as appropriate. Sclerotherapy should not be undertaken if significant valvular incompetence is suspected following the evaluation. Patients should have post-treatment follow-up to assess for the development of deep vein thrombosis. Sclerosants must never be injected intra-arterially because this can cause severe necrosis which may necessitate amputation. A vascular surgeon must be called in immediately if any such incident occurs. In certain body regions such as in the foot or malleolar region, the risk of inadvertent intra- arterial injection may be increased. Therefore, in these regions only small amounts should be used in low concentrations with particular care. Adverse effects, including tissue necrosis, may occur following extravasation, therefore it is important to exercise extreme care in intravenous needle placement and use the minimal effective volume at each injection site. All Aethoxysklerol products contain 5% (v/v) ethanol which may be harmful for those suffering from alcoholism or undergoing treatment of alcoholism with Disulfiram. To be taken into account in pregnant or breast-feeding women, children and high risk groups such as patients with liver disease or epilepsy.

Interactions: Lauromacrogol 400 is a local anaesthetic. When combined with other anaesthetics, there is a risk of an additive effect of these anaesthetics on the cardiovascular system.

Fertility, Pregnancy, and lactation: Safety for use in pregnancy has not been established. Studies in animals showed reproductive toxicity, but no teratogenic potential. Treatment should be postponed until after childbirth. Aethoxysklerol should be used only when clearly needed for symptomatic relief during pregnancy. It is not known whether lauromacrogol 400 is excreted in human milk. Caution should be exercised when used in nursing mothers. If sclerotherapy is necessary during breast-feeding, it is advisable to suspend breast-feeding for 2-3 days. It is not known whether lauromacrogol 400 affects fertility.

Undesirable effects: Refer to SmPC for full list of side effects. The most commonly reported side effects are temporary in most cases and include short-term injection site pain, injection site intravaricose blood clots and temporary skin discolouration after treatment.

Local adverse reactions (e.g., necrosis), especially of the skin and of the underlying tissue (and, in rare cases, of the nerves), were observed when treating varicose veins in the leg after inadvertent injection into the surrounding tissue (paravenous injection). The risk increases with increasing Aethoxysklerol concentrations and volumes. The most serious side effects reported in patients receiving lauromacrogol 400 are anaphylactic shock, pulmonary embolism, cerebrovascular accident, stress cardiomyopathy (Tako Tsubo) and cardiac arrest.

Common (≥1/100 to <1/10); neovascularisation, haematoma, skin hyperpigmentation, ecchymosis,
injection-site pain (short-term), injection-site thrombosis (local intravaricose blood clots).

Uncommon (≥1/1,000 to <1/100); thrombophlebitis superficial, phlebitis, dermatitis allergic, urticaria contact, skin reaction, erythema, necrosis of skin and tissues, induration, swelling, nerve injury.

Rare (≥ 1/10,000 to <1/1,000); migraine or visual disturbance (when using sclerosing microfoam), deep vein thrombosis, pain in extremity.

Very rare (<1/10,000); anaphylactic shock, angioedema, urticaria (generalised), asthma (asthmatic attack), cerebrovascular accident (stroke, transient ischaemic attack (TIA)), hemiparesis, headache, migraine, paraesthesia (local), hypoaesthesia oral, loss of consciousness, confusional state, aphasia, ataxia, dizziness, visual impairment (visual disturbance) cardiac arrest, palpitations, stress cardiomyopathy (Tako Tsubo), pulmonary embolism, syncope vasovagal, circulatory collapse, vasculitis, dyspnoea, chest discomfort, cough, dysgeusia, nausea, vomiting, hypertrichosis (in the area of sclerotherapy), pyrexia, hot flush, asthenia, malaise, blood pressure abnormal, heart rate abnormal (tachycardia, bradycardia).

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Kora Healthcare on 01904 217755 or pv@korahealthcare.com

Legal Classification: POM.

Marketing Authorisation Numbers, quantities, NHS prices: Aethoxysklerol 5mg/ml pack of 5 x 2ml ampoules £18.74 (PL 39972/0021), Aethoxysklerol 10 mg/ml pack of 5 x 2ml ampoules £22.38 (PL 39972/0022), Aethoxysklerol 30 mg/ml pack of 5 x 2ml ampoules £33.31 (PL 39972/0023).
Aethoxysklerol 2.5mg/ml (PL 39972/0024) and Aethoxysklerol 20mg/ml (PL39972/0025) are not currently marketed.

Marketing Authorisation Holder: Kora Corporation Ltd. t/a Kora Healthcare. 20 Harcourt Street, Dublin 2, D02 H364, Ireland.

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