PATIENT INFORMATION LEAFLET

Aterosklerol 1% Injectable Ampoule

For administration by IV injection only.

Sterile

Active Ingredient: 20 mg Lauromacrogol 400 per ampoule (2 mL)

Excipients: Ethanol 96%, Potassium dihydrogen phosphate, Disodium phosphate dihydrate, Water for injection

Read this entire PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to other.*
- *Should you visit a doctor or hospital during the period when you use this medicine, please tell your doctor that you use this medicine.*
- *Be very observant of the contents hereof. Do not use* ***more or less*** *than the doses prescribed for you.*

What is in this leaflet:

1. *What* Aterosklerol 1% Ampoule *is and what it is used for?*

• Aterosklerol 1% Ampoule contains 20 mg Lauromacrogol 400 per ampoule, as the active ingredient.

• Aterosklerol 1% Ampoule is a clear, colorless to extra light greenish yellow solution for injection and is available in packaging of 5 ampoules each containing 2 mL solution for injection.

• Aterosklerol 1% Ampoule belongs to a group of medicines administered by local injection for complete obliteration (sclerosing) of the intravascular space.

• Aterosklerol 1% Ampoule is used in the treatment of central veins of the spider veins, reticular varicose veins and the minor varicose veins by sclerotherapy. Sclerotherapy is a method of obliterating the vein lumen completely by injecting into the varicose vein a sclerosing solution.

2.. Before you use Aterosklerol 1% Ampoule

DO NOT USE Aterosklerol 1% Ampoule if you

- are allergic to Lauromacrogol 400 or to any of the other ingredients (please see the list of excipients) of Aterosklerol 1% Ampoule
- are a bedridden patient or unable to walk
- have severe arterial circulatory disorder (arterial occlusive disease Fontaine stage III or IV)
- have vascular occlusion due to a local or detached blood clot (thromboembolic diseases)
- have a high risk of developing blood clots in your veins or heart due to, e.g.: inherited blood disorders such as blood clotting, having hormonal contraception (contraceptive pills) or hormone replacement therapy, being significantly overweight, smoking, immobility for long duration
- have an acute severe disease in general (especially if untreated)

USE CAUTIOUSLY and check with your doctor before using Aterosklerol 1% Ampoule if you

- have arterial circulatory disorder (arterial occlusive disease Fontaine stage II),
- have oedema formation in the legs (if external compression fails to be effective),
- have high fever,
- have an inflammatory skin disease within the area being treated,
- have signs of occlusion in the smallest and slimmest veins, e.g. microangiopathy due to diabetes or neuropathy due to sensory loss.
- have reduced physical mobility,
- are in a very poor health condition in general,
- have attacks of labored breathing (bronchial asthma) or strong predisposition to allergies.

If any of these apply to you, even if it happened in any period in the past, please consult your doctor.

Using Aterosklerol 1% Ampoule with food and drink

No interaction with foods and drinks in terms of method of administration.

Pregnancy

Please consult your doctor or pharmacist before using the medicine.

There is no adequate information on the use of Aterosklerol 1% Ampoule in pregnant women.

It should not be used during pregnancy unless clearly necessary.

Please immediately consult your doctor or pharmacy should you come to know in the course of your treatment that you are pregnant.

Lactation

Please consult your doctor or pharmacist before using the medicine.

No investigation has been performed in humans on the excretion of Aterosklerol 1% Ampoule in the breast milk. Therefore, if treatment with Aterosklerol 1% Ampoule is necessary during lactation, it is advisable to suspend breast-feeding for 2-3 days.

Driving and using machinery

Aterosklerol 1% Ampoule has no known adverse effect on the ability to drive or operate machines.

Important information about some of the ingredients of Aterosklerol 1% Ampoule

Aterosklerol 1% Ampoule contains a trace amount (<100mg per dose of 2 mL) of ethanol (alcohol).

Aterosklerol 1% Ampoule contains < 1 mmol (39 mg) potassium per dose of 2 mL; that is to say “does not contain potassium” in fact.

Aterosklerol 1% Ampoule contains < 1 mmol (23 mg) sodium per dose of 2 mL; that is to say “does not contain sodium” in fact.

Drug Interactions

If you use Aterosklerol 1% Ampoule with other anesthetic drugs, it may pose a risk of intensifying the effects of such drugs on the cardiovascular system. Such effect is due to the fact that Lauromacrogol 400 is also a local painkiller (local anesthetic).

If you are currently using/taking or have used/taken recently any drug, prescribed or unprescribed, please tell your doctor or pharmacist about it.

3. How to use Aterosklerol 1% Ampoule

Instructions for proper use and dosage/frequency of administration

- In general the recommended dose of 2 mg Lauromacrogol 400 per kg body weight per day should not be exceeded. (for a patient weighing 70 kg, this would be a daily dose of up to 28 mL Aterosklerol 1% Ampoule). Your doctor will determine the dose of your medicine depending on your disease and administer it to you accordingly.
- When treating a patient with predisposition to hypersensitivity reactions for the first time, no more than one injection should be administered. Depending on the response, several injections may be administered in subsequent treatment sessions, provided that the maximum dose is not exceeded.
- Depending on the extent of the area to be treated, 0.1-0.2 mL Aterosklerol 1% Ampoule is injected intravenously.

Route and method of Administration:

- Aterosklerol 1% Ampoule injections must be administered directly into the vein (intravascularly)
- Please read the section provided at the end of this leaflet and intended for the health care professionals for information about how to administer Aterosklerol 1% Ampoule.

Different age groups:

Children:

No information

The elderly:

No information

Special conditions for use:

Renal / Liver Failure:

No information

Please tell your doctor or pharmacist if you think that the effect of Aterosklerol 1% Ampoule is very strong or weak.

If you use more Aterosklerol 1% Ampoule than you should:

Overdose (due to very high volume or concentration) may cause local tissue death (necrosis) especially following the inadvertent injection into the surrounding tissue (paravenous injection)

Please tell your doctor or a pharmacist if you have used more Aterosklerol 1% Ampoule than you need to use.

If you have omitted using Aterosklerol 1% Ampoule

Never use double dose to compensate any omitted doses.

Effects which may occur when treatment with Aterosklerol 1% Ampoule is terminated

N.A.

4. Possible Side Effects?

Like all medicines, Aterosklerol 1% Ampoule can cause side effects in patients having sensitivity to its ingredients. Local adverse reactions (e.g. necroses), 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 increased Aterosklerol 1% Ampoule concentrations and volumes.

Adverse reactions are categorized as follows:

Very common: more than 1 out of 10 subjects treated

Common: less than 1 out of 10, but more than 1 out of 100 subjects treated

Uncommon: less than 1 out of 100, but more than 1 out of 1000 subjects treated

Rare: less than 1 out of 1000, but more than 1 out of 10000 subjects treated

Very rare: less than 1 out of 10000 subjects treated

Immune System disorders

Very rare: anaphylactic shock (life threatening allergic reaction, symptoms are e.g. sudden breathing difficulties, blood pressure drop), angio-oedema (symptoms include sudden swellings, especially in the face, e.g. of the eyelids, lips or larynx), generalized hives (urticaria), asthma (asthma attack).

Nervous System Disorders

Very rare: Cerebrovascular event, headache, migraine, local sensory disturbances (paraesthesia), loss of consciousness, confusion and dizziness.

Eye Disorders

Very rare: Visual disturbances

Cardiac disorders

Very rare: Heart attack, tachycardia or arrhythmias (palpitation)

Vascular disorders

Common: occurrence of blood vessels in the area of sclerosation which were not visible prior to treatment (neovascularisation), hematomas

Uncommon: superficial venous inflammation (superficial thrombophlebitis, Phlebitis)

Rare: Deep vein thrombosis (possibly due to the underlying disease)

Very rare: pulmonary embolism, cardiovascular problems (vasovagal syncope), circulatory collapse, inflammation of the blood vessel wall (vasculitis)

Respiratory, Thoracic and Mediastinal disorders

Very rare: respiratory distress (dyspnoea), sensation of pressure in the chest, cough

Gastrointestinal Disorders

Very rare: Taste disorders, nausea

Skin and subcutaneous tissue disorders

Common: discoloration of the skin (hyperpigmentation), cutaneous hemorrhage (ecchymosis)

Uncommon: allergic inflammation of the skin (dermatitis), hives (contact urticaria), skin reactions, reddening (erythema)

Very rare: excessive growth of hair (hypertrichosis) in the sclerotherapy applied area

Musculoskeletal disorders, Connective Tissue and bone diseases

Rare: Arm and leg pains

General disorders and administration site conditions

Common: pain locally at the injection site (short-term), thrombosis at the injection site (local intravariceal blood clots)

Uncommon: local tissue death (necrosis), induration of tissue, swelling

Very rare: fever, reddening in the face, unusual weakness (asthenia),

Investigations

Very rare: Abnormal blood pressure

Injury and poisoning

Uncommon: Nerve injuries

Reporting of side effects

If you experience any side effect, tell your doctor, pharmacist or nurse. Also you can report any side effects directly to Turkiye Farmakovijilans Merkezi (TUFAM) by clicking on the link "Side Effect Reporting" at www.titck.gov.tr or by calling side effect reporting line 0800 314 00 08. You will have contributed to access to more information about the safety of the medicine by reporting any occurring side effects.

If you experience any side effect not mentioned in this patient information leaflet, please keep your doctor or pharmacist informed.

5. How to store Aterosklerol 1% Ampoule

Keep Aterosklerol 1% Ampoule out of reach and sight of children, in its original pack.

Store in room temperature below 25°C. Do not use if you notice any precipitate.

Regard the expiry date.

Do not use Aterosklerol 1% Ampoule after the expiry date shown on the outer packaging / use before the expiry date.

Do not use Aterosklerol 1% Ampoule if you notice any imperfections in the packaging and/or the contents.

Do not dispose of any expired or disused medicines via wastewater or household waste! Discard to the collection system designated by the Ministry of Environment and Urbanization.

Licensee (manufacturer and marketing authorization holder):

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Manufactured at:

Rompharma İlaç Sanayi ve Tic. Ltd. Şti.

G.O.P Mah. COSB 5. Cad, No: 17

Cerkezkoy / Tekirdag

This leaflet was last approved on …./…./…..

THE FOLLOWING INFORMATION IS INTENDED FOR THE HEALTHCARE PROFESSIONALS TO ADMINISTER THIS MEDICINE

HOW TO ADMINISTER

- This medicinal product is for single use only. Any remaining product after use must be disposed of.
- Independently of the pattern of introducing the needle into the vein (only by cannula while the patient is standing or by a syringe ready for injection while the patient is sitting), the injection should only be carried out in a leg placed horizontally or elevated approximately 30-45° above the horizontal.
- Injections of Aterosklerol 1% Ampoule must be given strictly into the vessel (intravascularly).
- Very fine needles (e.g. insulin needles) and smooth-moving syringes are used. The puncture is carried out with a small puncture angle until the needle is positioned intravenously.
- Depending on the sizes and degrees of varicose veins, several therapy sessions may be required at intervals of 1-2 weeks.
- Once the injection site has been covered, a tight compression bandage or elastic stocking must be applied. After that, the patient should walk for 30 minutes, preferably within the reach of the practice.
- Compression should be applied for 5-7 days. For extensive varicosis, longer compression treatment with short traction bandages is recommended.
- To make sure the bandage does not slip, especially on the thigh and conical limbs, a foam bandage support under the actual compression bandage is recommended.
- The success of sclerotherapy depends on a thorough and careful follow-up compression treatment.

IMPORTANT PRECAUTIONS FOR USE

- Sclerosants (medications used in treatment by sclerotherapy) must never be injected into an artery (intra-arterially) because this can cause extended tissue death

(necrosis) which may necessitate amputation. A vascular surgeon must be called in immediately if any such incidents occur.

- An indication in the facial area must be strictly evaluated for all sclerosants because intravascular injection can lead to pressure reversal in the arteries and hence to irreversible visual disturbances (blindness).
- In certain body regions such as in the foot or malleolar 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.