PACKAGE LEAFLET

VEINDOCANOL % 3 Solution for Injection
I.V
Sterile

60 mg Lauromacrogol 400 (Polidocanol) / 2 mL

Read all of this leaflet carefully before you receive this injection
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *Do not give to others; this drug is prescribed for you personally.*
- *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.*
- *Followed the instruction written in this leaflet. Do not use **high** or **low** doses other than the recommended dose for the drug.*

In this leaflet:

1. What VEINDOCANOL % 3 is and what it is used for?
• VEINDOCANOL % 3 contains 60 mg of Lauromacrogol 400 as active ingredient on each ampoule.
• VEINDOCANOL % 3, clear, colorless to very faintly greenish yellow solution for injection and it is marketed as 5/2 mL ampoules in a box.
• VEINDOCANOL % 3 is included in a group of drugs that are administered by local injection and which provide complete closure of the vessel lumen (sclerosing)
• VEINDOCANOL 1% is used for sclerotherapy of medium-sized to large varices, and sclerotherapy of haemorrhoidal disease (1st and 2nd degree). Sclerotherapy is a method of completely closing the vessel lumen by injecting a sclerosing solution into the varicose vein.

2. Before you use VEINDOCANOL % 3
• Sclerosans (drugs used for treatment with sclerotherapy) should never be injected into the artery. Because this application may cause widespread tissue death (necrosis), which may require surgical interruption of the relevant section. A vascular surgeon should be called immediately if such an event occurs.
• For all sclerosans, the facial area symptoms should be carefully evaluated because intravenous injection can lead to reversal of pressure in the arteries, thus causing irreversible vision loss (blindness).
• In certain areas of the body, such as the foot or wrist area, there may be a high risk of accidental injection into the artery. In these regions, only small amounts should be used during treatment and care should be taken.

Do not use VEINDOCANOL % 3
If:
- in patients with known allergy to Lauromacrogol 400 or any of the other ingredients of VEINDOCANOL % 3
- in patients with acute severe disease (especially if untreated)

Do not use VEINDOCANOL % 3% for sclerotherapy of varicose veins
If:
- in bedridden patients or patients who are unable to walk
- in patients with severe arterial circulatory disorder (arterial occlusive disease Fontaine stage III and IV)
- in patients with vascular occlusion due to a local or detached blood clot (thromboembolic diseases)
- in patients with a high risk of vascular occlusions (thrombosis), e.g. patients with congenital predisposition to blood clots or with multiple risk factors such as the use of hormonal contraceptives (e.g. the pill) or hormone replacement therapy, overweight, smoking, extended periods of immobility.

Do not use VEINDOCANOL % 3% for sclerotherapy of haemorrhoidal disease
If:
- in patients with acute inflammations in the anal region

Take special care with VEINDOCANOL % 3
If:
- in patients with attacks of laboured breathing (bronchial asthma) or strong predisposition to allergies
- in patients with febrile states
- in patients with very poor general health

Take special care with VEINDOCANOL % 3 for sclerotherapy of varicose veins
If:
- in patients with swollen legs with accumulation of aqueous fluid (leg oedema), if it cannot be influenced by compression
- in patients with inflammatory skin disease in the area of treatment
- in patients with symptoms of an occlusion of smallest and tiniest arterial vessels e.g. due to diabetes (microangiopathy) and impaired sensation (neuropathy)
- in patients with reduced mobility

Take special care with VEINDOCANOL % 3 for sclerotherapy of haemorrhoidal disease
If:
- in patients with choronic inflammatory bowel disease (e.g. Crohn's disease)
- in patients with known excessive coagulability of blood (hypercoagulability)

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Pregnancy
Consult your doctor or pharmacist before using this medication.
There are no adequate data from the use of VEINDOCANOL % 3 in pregnant women. VEINDOCANOL % 3 should not to be use during pregnancy unless clearly necessary. Studies in animals did not show any evidence of teratogenic effects.
If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast feeding
Consult your doctor or pharmacist before using this medication.
If you need to use VEINDOCANOL % 3 during lactation, it is advisable to suspend breast-feeding for 2-3 days, since investigations on the excretion of Lauromacrogol 400 in the breast milk have not been performed in humans.

Driving and using machines
No negative effects on the ability to drive and use machines are known for VEINDOCANOL % 3

Important information about some of the ingredients of VEINDOCANOL % 3
VEINDOCANOL % 3 contains 5% (v/v) alcohol. This must be taken into account in patients with previous alcoholism or treatment of alcoholism with disulfiram.
VEINDOCANOL % 3 contains potassium, but less than 1 mmol (39 mg) per ampoule, i.e. essentially 'potassium-free'.
VEINDOCANOL % 3 contains sodium, but less than 1 mmol (23 mg) per ampoule, i.e. essentially 'sodium-free.

Using other medicines
• The active ingredient lauromacrogol 400 is also a local painkiller (local anaesthetic). Therefore, when combined with other anaesthetics, there is a risk of intensifying the effect of the anaesthetics on the cardiovascular system.
Please inform your doctor or pharmacist if you are currently using any prescription or non-prescription medication or if you have recently used it.

3. How to use VEINDOCANOL % 3?
Dosage
• Generally, the 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 VEINDOCANOL % 3).
• 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.
Sclerotherapy of medium-sized varices:
• Depending on the diameter of the varices to be treated, VEINDOCANOL % 2 or % 3 is used. In the first treatment, only one injection of 0.5-1 mL VEINDOCANOL % 2 or % 3 should be administered.
• Depending on the outcome and the length of the segment to be treated, several injections with up to 2 mL per injection may be administered in subsequent treatment sessions, provided that the maximum dose is not exceeded.
Sclerotherapy of large varices
• In the first treatment, only one injection of 1 ml VEINDOCANOL % 3 is administered. Depending on the outcome and the length of the segment to be treated, several injections (2-3) with up to 2 mL per injection may be administered in subsequent treatment sessions, provided that the maximum dose is not exceeded.
Sclerotherapy of haemorrhoidal disease
• During one treatment session, a total of 3 ml VEINDOCANOL % 3 should not be exceeded.
• Depending on the findings, a maximum of 1.0 mL per haemorrhoid is administered as a strictly submucous injection.
• When treating an 11 o'clock haemorrhoid in men, the quantity injected must not exceed 0.5 mL

Method of administration
• Injections of VEINDOCANOL % 3 must be given strictly into the vessel (intravascularly) for the sclerotherapy of medium-sized and large varicose veins.
• The injection must be strictly submucous (beneath the mucous membrane) and given directly into the haemorrhoid or above (cranial to) it into the surrounding tissue of the feeding vessels.
• Refer to VEINDOCANOL % 3 for information on how to apply, at the end of this manual and for medical personnel.

Use in special population
Pediatric use:
No data
Geriatric use:
No data
Renal / Hepatic failure
No data
If you have an impression that VEINDOCANOL % 3 effects is too strong or too weak, talk to your doctor or pharmacist.

If more VEINDOCANOL % 3 is used than recommended
Sclerotherapy of varicose veins
Overdose (caused by the volume or concentration being too high) may cause local tissue death (necrosis), especially after paravenous injection.
Sclerotherapy of haemorrhoidal disease
Overdose may result in local tissue death (necrosis), probably

extending to the surrounding tissue.
If you forget to use VEINDOCANOL % 3
Do not use a double dose to compensate for forgotten doses.
VEINDOCANOL Effects that may occur when the treatment is terminated with 1%
None.

4. Possible Side Effects
Like all medicines, VEINDOCANOL % 3 can cause side effects, although not everybody gets them.
Sclerotherapy of varicose veins
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 varices in the leg after inadvertent injection into the surrounding tissue (paravenous injection). The risk increases with increasing Veindocanol concentrations and volumes.
In addition, the following adverse reactions were observed with the frequencies seen below:
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 1,000 subjects treated
Rare: Less than 1 out of 1,000, but more than 1 out of 10,000 subjects treated
Very rare: Less than 1 out of 10,000 subjects treated
Not known: Cannot be estimated from the available data
Immune system disorders
Very rare: Anaphylactic shock (sudden life-threatening allergic reaction, symptoms are e.g. sudden breathing difficulties, dizziness, blood pressure drop); angioedema (symptoms include sudden swellings, especially in the face, e.g. of the eyelids, lips or larynx); hives (generalised urticaria); asthma (asthmatic attack).
Nervous system disorders
Very rare: Stroke (cerebrovascular accident), headache, migraine, local sensory disturbances (local paraesthesia), loss of consciousness, confusion, dizziness.
Eye disorders
Very rare: visual impairment (visual disturbance)
Cardiac disorders
Very rare: Cardiac arrest, fast or irregular heartbeats (palpitations)
Vascular disorders
Common: Occurrence of blood vessels in the area of sclerosation which were not visible prior to treatment (neovascularisation); bruise (haematoma
Uncommon: Venous inflammation (superficial thrombophlebitis, phlebitis)
Rare: Deep vein thrombosis (possibly due to the underlying disease)
Very rare: Blockage of lung artery (pulmonary embolism); fainting (vasovagal syncope); circulatory collapse; inflammation of the blood vessel wall (vasculitis)
Respiratory, thoracic and mediastinal disorders
Very rare: Difficulty in breathing (dyspnoea); sensation of pressure in the chest; cough
Gastrointestinal disorders
Very rare: Taste disorders; nausea
Skin and subcutaneous tissue disorders
Common: Discolouration of the skin (hyperpigmentation); cutaneous haemorrhage (ecchymosis)
Uncommon: Allergic inflammation of the skin (dermatitis); hives (contact urticaria); skin reaction; redness of the skin (erythema)
Very rare: Excessive growth of hair (hypertrichosis) in the area of sclerotherapy)
Musculoskeletal, connective tissue and bone disorders
Rare: Pain in extremity
General disorders and administration site conditions
Common: Pain at the injection site (short-term); thrombosis at the injection site (local intravaricose blood clots)
Uncommon: Local tissue death (necrosis); induration of tissue; swelling
Very rare: Fever; hot flush; unusual weakness (asthenia); generally feeling un-well (malaise)
Investigations
Very rare: Abnormal blood pressure
Injury, poisoning and procedural complications
Uncommon: Nerve injury
Sclerotherapy of haemorrhoidal disease
When treating haemorrhoidal disease, local adverse reactions such as burning, pain, discomfort, and pressure sensation were observed during and after injection, especially in the 11 o'clock position in men (prostate region). These reactions are of a temporary nature and may last for 2-3 days in rare cases. Sclerotherapy of haemorrhoidal disease is painless if the proper technique is used, since there are no sensitive nerve fibres in the region of injection.
The following adverse reactions were observed with the frequencies seen below:
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 1,000 subjects treated
Rare: Less than 1 out of 1,000, but more than 1 out of 10,000 subjects treated
Very rare: Less than 1 out of 10,000 subjects treated
Not known: Cannot be estimated from the available data
Immune system disorders
Very rare: anaphylactic shock, angioedema (symptoms include sudden swelling, especially in the face, e.g. of the eyelids, lips or larynx), hives (urticaria generalized), asthma (asthmatic attack)
Nervous system disorders
Very rare: loss of consciousness, dizziness
Cardiac disorders
Very rare: Fast or irregular heartbeats (palpitations)
Vascular disorders
Very rare: Fainting (syncope vasovagal), circulatory collapse.
Respiratory, thoracic and mediastinal disorders
Very rare: dyspnoea, chest discomfort, cough
Gastrointestinal disorders
Very rare: nausea
Skin and subcutaneous tissue disorders
Uncommon: inflammation of the anus and/or rectum (proctitis); itching of the skin around the anüs (anal pruritus); allergic inflammation of the skin (allergic dermatitis); hives (contact urticaria); skin reaction
Reproductive system and breast disorders
Very rare: impairment of erection
General disorders and administration site conditions
Common: mucosal burning sensation, injection site pain, discomfort, sensation of pressure
Uncommon: induration of tissue
Rare: Local tissue death (necrosis); rarely with extension into the surrounding tissue; bleeding at the injection site; thrombosis at the injection site (intraheamorrhoidal)
Investigations
Very rare: blood pressure abnormal
If you encounter any side effects not mentioned in these instructions, please inform your doctor or pharmacist.

5. How to store VEINDOCANOL % 3
VEINDOCANOL % 3 should be kept out of the reach and sight of children
Do not store above 30°C.

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THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO WILL APPLY THIS PRODUCT
APPLICATION
• This product is for single use. The remaining part must be discarded after use
• Regardless of the way the needle is inserted into the vein (only when the patient is with the cannula or while the patient is sitting with a syringe ready for injection), Injections should only be carried out in a leg placed horizontally or elevated 30–45 ° above the horizontal.
• Injections of VEINDOCANOL % 3 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 degree and extent of the varices, several treatments 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 reach of the practice.
• When used for sclerotherapy of spider veins and central veins of spider veins, compression should be applied for 2-3 days after sclerotherapy of spider veins, otherwise 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 relies on thorough and careful follow-up compression treatment.

IMPORTANT PRECAUTIONS FOR USE
• Sclerosants 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 incident occurs.
• 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.