

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed without a doctor's prescription

Venoruton Capsules 300 mg

Active ingredient

Each capsule contains:
oxerutines 300 mg

Inactive ingredients and allergens in this medicine: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Take this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need additional information. You must contact a doctor if your symptoms worsen or do not improve.

1. What is this medicine intended for?

Helps treat varicose veins (swollen veins).

Therapeutic group: bioflavonoids

This medicine is used to relieve symptoms resulting from leg vein disorders (chronic venous insufficiency). It has an anti-oedematous effect, which reduces tissue fluid accumulation (swelling or oedema) in the legs and thus relieves symptoms such as heavy legs, fatigue, tension and tingling in the legs.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).
- You are in the first trimester of pregnancy.

Special warnings about using this medicine

Talk to your doctor or pharmacist before taking Venoruton Capsules 300 mg.
There are no special precautions.

Children and adolescents

No data are available about use in children and adolescents under 18 years of age, therefore use is not recommended in this age group.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food

Swallow the medicine with water, with or after a meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

Pregnancy

If you are pregnant or planning to become pregnant, you should take Venoruton Capsules 300 mg only after consultation with your doctor, only if absolutely necessary and only from the fourth month of pregnancy onwards, as there is insufficient experience with this medicine in the first months of pregnancy.

Breast-feeding

There have been no human studies on the passage of the active ingredient into human milk. Traces of the active ingredient found in breast milk in animal experiments are of no clinical significance and are therefore probably harmless for infants.

Driving and using machines

In very rare cases tiredness and dizziness have been reported. If you are tired or dizzy, do not drive or operate dangerous machines.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually: one capsule 2-3 times a day.

Take the capsules unchewed with some liquid during or immediately after meals.

Do not exceed the recommended dose.

Treatment duration

The duration of treatment depends on the symptoms.

The same dosage should be continued until symptoms resolve, but no longer than 3 months. If symptoms persist, treatment can be continued for a prolonged period of time after consultation with a doctor.

Success of the treatment depends largely on consequent adherence to the prescribed dosage and duration of treatment.

Patients with cardiac, renal or hepatic impairment

Venoruton is not intended for patients with oedema of the lower limbs due to cardiac, kidney or liver disorders, because the safety and efficacy of Venoruton have not been established in these patients.

If you forget to take the medicine at the scheduled time

Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

If you interrupt your treatment or stop taking the medicine too soon, the desired effect will not be obtained or your symptoms will worsen again. Therefore, consult your doctor if you wish to stop or interrupt your treatment.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Venoruton Capsules 300 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Rare side effects - effects that appear in 1-10 in 10,000 users

- Gastrointestinal disorders
- Allergic skin reactions, itching, hives

Very rare side effects - effects that appear in less than one in 10,000 users

- Hypersensitivity reactions, including anaphylactoid reactions
- Dizziness, headache
- Flushing (facial redness)
- Fatigue

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/blister tray. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C, protect from moisture.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Capsule core:

Macrogol 6000

Capsule coating:

Gelatin; water; titanium dioxide; yellow iron oxide; sodium laurilsulfate; black ink (shellac glaze in ethanol, isopropyl alcohol, iron oxide black, N-butyl alcohol, propylene glycol, ammonium hydroxide 28%).

What the medicine looks like and contents of the pack:

Yellow-beige hard gelatin capsule, with imprint "Venoruton 300".

Each pack contains 20 capsules in a blister tray.

Registration holder's name and address: Devries & Co. Ltd., 32 Habarzel Street, Tel Aviv

Manufacturer's name and address:

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad-Vilbel, Germany

Registration number of the medicine in the Ministry of Health's National Drug Registry:

115-96-22946

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