Package leaflet: Information for the user

Venoruton 1000 mg, effervescent tablets
O-(beta-hydroxyethyl)-rutosides

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What Venoruton is and what it is used for

Venoruton contains O-(ß-hydroxyethyl)-rutosides that belong to the group of medicines for protecting blood vessels (called 'systemic vasoprotectors').
Venoruton stabilises the walls of blood vessels, reducing vessel permeability and consequent swelling.

How Venoruton works
Relieves ankle swelling caused by chronic venous insufficiency on feet. Patients with varicose veins or other foot vein problems develop excessive leakage from small blood vessels, which causes swelling in the ankle region. Venoruton reduces swelling and relieves the associated symptoms, such as pain, fatigue, heavy feet, swelling, restless feet, paraesthesia (tingling or buzzing), cramps. Patients with these symptoms are also advised to wear elastic supports (usually stockings); it has been found that Venoruton has a beneficial effect in this situation.
Venoruton acts on the smallest blood vessels (capillaries), reducing the leakage of water and other substances through vessel walls.

2. What you need to know before you use Venoruton

Do not use Venoruton:
- if you are allergic to O-(beta-hydroxyethyl)-rutosides or any of the other ingredients of Venoruton (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Venoruton:
- if the swelling in your feet is caused by heart, kidney or liver problems.

You should not use Venoruton in those cases, because it is ineffective for these indications.

Children and adolescents
It is not recommended to use oral Venoruton in children.

Other medicines and Venoruton
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including over-the-counter medicines or food supplements.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
According to general safety precautions, it is not recommended to use Venoruton in the first trimester of pregnancy.

Driving and using machines
Venoruton has no or only a limited effect on the ability to drive and use machines.

There have been rare reports of patients experiencing fatigue and dizziness after taking this medicine. If this happens to you, you are advised not to drive or operate machinery.

Venoruton 1000 mg effervescent tablets contain:
Sodium: This medicine contains 3.56 mmol (82 mg) of sodium per tablet. This should be taken into account for patients who are on a reduced-salt diet.

Potassium: This medicine contains 10.15 mmol (396 mg) of potassium per tablet. This should be taken into account for patients with impaired renal function who are on a reduced-salt diet.

3. How to take Venoruton

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Make sure to follow the instructions below.

Chronic venous insufficiency in feet
Initial dose
- 1 effervescent tablet once a day.
- Dissolve the effervescent tablet in a glass of water.

Maintain this dose until the symptoms and swelling are completely gone. Symptoms usually disappear after 2 weeks of treatment.

To consolidate the outcome of treatment, continue maintenance treatment with the same dose or the minimum maintenance dose of 500-600 mg once a day (corresponds to one Venoruton Forte 500 mg tablet).

Treatment may be discontinued after complete disappearance of the symptoms and swelling. If symptoms reappear, continue treatment with the same dose or the minimum maintenance dose of 500-600 mg Venoruton per day.

If symptoms do not improve or worsen after 2 weeks, discontinue treatment and talk to your doctor.

This medicine is not suitable for children under 18 years of age.

If you take Venoruton more than you should
Contact your doctor immediately if you have accidentally taken too much Venoruton.

If you forget to take Venoruton
Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be severe and are very rare *(may affect up to 1 in 10,000 people)*.

Discontinue using Venoruton and seek immediate medical attention if you have any of the following side effects, which can be symptoms of an allergic reaction:
- breathing or swallowing difficulties;
- swelling of face, lips, tongue or throat;
- severe itching of the skin with red rash, rash with blisters.

If you experience any of the above symptoms, stop using the medicine and seek immediate medical attention.

Other reactions are generally mild.

Some side effects are rare (*may affect up to 1 in 1,000 people*):
Gastrointestinal problems (incl. flatulence, diarrhoea, stomach ache, stomach discomfort, dyspepsia), rash, itching or hives.

Some side effects are very rare (*may affect up to 1 in 10,000 people*):
Dizziness, headache, fatigue, flushing.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Venoruton

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton.
The expiry date refers to the last day of that month.

Do not store above 30°C. Close the tube tightly and keep it away from humidity.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Venoruton contains
- The active substances are O-(beta-hydroxyethyl)-rutosides.

1 tablet contains 1000 mg of O-(β-hydroxyethyl)-rutosides (HR).

- The excipients are:

anhydrous citric acid, potassium carbonate, potassium hydrogen carbonate, sodium hydrogen carbonate, macrogol 6000, potassium acesulfame, povidone, orange flavour, magnesium stearate.

What Venoruton looks like and contents of the pack
Yellow, round, biconvex, effervescent tablets with a round edge. Polypropylene tube and polyethylene cap with a desiccant.
Pack size: 15, 30 or 60 tablets per pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Germany

Manufacturers
GlaxoSmithKline Consumer Healthcare GmbH & Co. KG
Barthstraße 4
80339 Munich,
Germany

or

STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

UAB „STADA Baltics“
Goštauto 40A
03163 Vilnius
Lithuania
e-post: ofisas@stada.lt

This leaflet was last revised in January 2021.