Package leaflet: Information for the patient

Flebaven 1000 mg tablets
micronized diosmin

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 or pharmacist if you do not feel better or if you feel worse after 6 weeks of treatment of chronic venous disease or after 7 days of treatment of acute hemorrhoidal attack.

What is in this leaflet

1. What Flebaven is and what it is used for

Diosmin belongs to a group of substances called bioflavonoids and is used for capillary stabilization. Flebaven contains active substances affecting vein activity and protecting veins; they increase the tone of veins and the resistance of capillaries. Flebaven reduces the occurrence of oedema and has anti-inflammatory effects.

Flebaven is indicated
- in adults for the treatment of signs and symptoms of chronic venous disease, such as pain, feeling of heaviness, leg tiredness, restless legs, night cramps, oedema and trophic changes.
- for the treatment of symptoms related to acute haemorrhoidal disease, such as pain, bleeding and swelling in the anal region.

You must talk to your doctor or pharmacist if you do not feel better or if you feel worse after 6 weeks if you are taking Flebaven for the treatment of the symptoms of chronic venous disease.
If you are taking Flebaven to treat symptoms of acute hemorroidal disease you should talk to your doctor or pharmacist if you do not feel better or you feel worse after 7 days.

2. What you need to know before you take Flebaven

Do not take Flebaven:
- if you are allergic to diosmin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Flebaven.

Chronic venous disease
If your condition worsens during treatment, which can manifest as skin or vein inflammation, hardening of the tissue under the skin, severe pain, skin ulcers or atypical symptoms such as sudden swelling of one or both legs, you should consult your doctor immediately.

Treatment with Flebaven is most beneficial when accompanied by a balanced lifestyle:
- sun exposure and prolonged standing should be avoided,
- appropriate weight should be maintained,
- wearing special stockings might improve circulation in some patients.

Flebaven will not help in reducing the swelling in your lower libs if this is caused by heart, kidney or liver disease.

Acute hemorrhoidal disease
If you have an acute attack of haemorrhoids, you may take Flebaven only for a limited time of 15 days. If symptoms do not subside in this time, consult your doctor.

If the condition worsens during treatment, i.e. if you notice increased bleeding from the rectum, blood in stools or are in doubt about bleeding haemorrhoids, consult your doctor.

Treatment with Flebaven is not a substitute for the specific treatment of other anal disorders.

Children and adolescents
The use in children and adolescents is not recommended.

Other medicines and Flebaven
So far no interactions of diosmin and other medicinal products have been reported. However, you should still tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Flebaven with food
You should take Flebaven with meals.

Pregnancy and breast-feeding
The safety of use of Flebaven during pregnancy and breast-feeding has not been established. Therefore, its use during these periods is not recommended.
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 any medicine.

Driving and using machines
Flebaven has no or negligible influence on the ability to drive and use machines.

Flebaven contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per daily dose, that is to say essentially ‘sodium-free’.

3. How to take Flebaven

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.

Posology
- **Chronic venous disease**
  The recommended daily dose is 1 tablet.
  You must take this medicine for at least 4 to 5 weeks before improvement can be expected. If

the symptoms of your disease get worse or do not improve after six weeks of treatment, you should consult your doctor.

- **Acute hemorrhoidal disease**
  The recommended daily dose in the first 4 days of treatment is 3 tablets.
  During the following 3 days, the recommended daily dose is 2 tablets.
  Afterwards, the recommended dose for maintenance treatment is 1 tablet daily.
  If the symptoms do not improve or get worse after 7 days of treatment, you should consult with your doctor. Self-treatment with Flebaven can last for a period of 15 days; if symptoms have not resolved during this time, you should consult with your doctor.

Method of administration
Flebaven should be taken with meals.
Swallow the tablet with some liquid.

If you take more Flebaven than you should
If you have taken more tablets than you should, talk to your doctor or pharmacist.
So far, no cases of overdose with diosmin have been reported.

If you forget to take Flebaven
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. Side effects reported with diosmin include:

Common (may affect up to 1 in 10 people):
- Diarrhoea, indigestion, nausea (feeling sick), vomiting.

Uncommon (may affect up to 1 in 100 people):
- Colitis (inflammation of the colon).

Rare side (may affect up to 1 in 1,000 people):
- Headache, malaise (feeling unwell), vertigo (a spinning sensation),
- Rash, itching, urticaria (hives).

Not known (frequency cannot be estimated from the available data):
- Abdominal pain,
- Oedema (swelling of the face, lips and eyelids), exceptionally angioedema (rapid swelling of tissues, such as the face, lips, tongue or throat, which may result in difficult breathing).

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 Flebaven

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 packaging after EXP. The expiry

date refers to the last day of that month.

Do not store above 25 °C.
Store in the original packaging in order to protect from moisture.

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 Flebaven contains
- The active substance is micronized diosmin. Each tablet contains 1000 mg micronized diosmin.
- The other ingredients are polyvinyl alcohol, croscarmellose sodium and magnesium stearate. See section 2 "Flebaven contains sodium".

What Flebaven looks like and contents of the pack
Pale greenish or greyish yellow to pale greenish or greyish brown marbled, slightly biconvex oval tablets. Dimensions of tablets are defined by 18.0 mm × 9.0 mm oval shaped punches.

Flebaven is available in packs containing 20, 30, 60, 90 and 120 tablets in blisters.

Not all pack sizes may be marketed.

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