

Package leaflet: Information for the patient

Hesio, 500 mg film-coated tablets

micronized flavonoids, as diosmin and other flavonoids, expressed as hesperidin

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 7 days.

What is in this leaflet

1. What Hesio is and what it is used for
2. What you need to know before you take Hesio
3. How to take Hesio
4. Possible side effects
5. How to store Hesio
6. Contents of the pack and other information

1. What Hesio is and what it is used for

Hesio is a vasoprotector. It increases venous tone and the resistance of small blood vessels.

Hesio is indicated in adults:

- for the treatment of symptoms related to the chronic venous insufficiency of the lower extremities: heaviness of legs, swollen legs, pain, nocturnal leg cramps (pain that occur in the legs during the night).
- for the treatment of functional symptoms related to acute hemorrhoidal crisis, such as pain, bleeding and swelling in the anal region.

2. What you need to know before you take Hesio

Do not take Hesio

- If you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Hesio.

Chronic venous disease:

In case of venous insufficiency, the treatment should be combined with a healthy lifestyle for getting the best results. Avoid exposure to sun, heat, prolonged standing or becoming overweight. Walking and wearing special (compression) socks improves circulation.

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, talk to your doctor immediately.

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

Acute hemorrhoidal disease

If you have an acute attack of haemorrhoids, you may take Hesio only for a limited time of 7 days. If symptoms of acute hemorrhoidal crisis do not disappear within 7 days, talk to your doctor.

If the condition worsens during treatment, that is if you notice increased bleeding from the rectum, blood in stools or are in doubt about bleeding haemorrhoids, consult your doctor.
Treatment with Hesio is not a substitute for the specific treatment of other anal disorders.

If you have any questions, ask your doctor or pharmacist.

Children and adolescents

Hesio is not recommended for use in children and adolescents.

Other medicines and Hesio

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No interactions with other medicines are presently known.

Pregnancy and breast-feeding

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.

As a general precautionary measure, it is preferable to avoid the use of this medicine during pregnancy and breast-feeding. Due to lack of data concerning excretion into breast milk, taking this medicine is not recommended during breast-feeding.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

3. How to take Hesio

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.

Chronic venous insufficiency

The recommended dose for adults is two tablets a day for 2 months, one tablet at noon and one tablet in the evening with a meal. Treatment might be continued for further 2 months if justified by persistence of symptoms.

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 Hesio for the treatment of the symptoms of chronic venous disease. If you need to take Hesio further, the length of treatment will be decided by your doctor.

Acute haemorrhoidal crisis

During the first 4 days of treatment, the recommended dose for adults is 3 tablets twice daily (6 tablets a day). During the following 3 days, the dose is 2 tablets twice daily (4 tablets a day).

Take these tablets with a meal.

If you are taking Hesio to treat symptoms of acute hemorrhoidal disease talk to your doctor or pharmacist if you do not feel better or you feel worse after 7 days.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

If you take more Hesio than you should

If you have taken more tablets than you should, talk to your doctor or pharmacist.

There is limited experience with micronized flavonoids overdose. The adverse events in overdose could be diarrhoea, nausea, abdominal pain, pruritus, rash.

If you forget to take Hesio

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.

Common (may affect up to 1 in 10 people):

- nausea, vomiting, diarrhoea, dyspepsia.

Uncommon (may affect up to 1 in 100 people):

- inflammation of the colon.

Rare (may affect up to 1 in 1,000 people):

- headache, dizziness, malaise, rash, pruritus, urticaria.

Not known (frequency cannot be estimated from the available data):

- isolated oedema of the face, lip or eyelids in association with allergic symptoms. Exceptionally Quincke's oedema may develop (the rapid evolving oedema of the face, lips, mouth, tongue or pharynx, which may be accompanied by breathing difficulties).
- abdominal pain.

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 Hesio

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date ("EXP") which is stated on the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Hesio contains

- The active substance is micronized flavonoids, as diosmin and other flavonoids expressed as hesperidin.
Each film-coated tablet contains 500 mg of micronized flavonoids, as 450 mg diosmin and 50 mg other flavonoids expressed as hesperidin.
- The other ingredients are:
Tablet core: microcrystalline cellulose (Type 102), gelatin, maize starch, talc, magnesium stearate.
Tablet coating: partially hydrolysed poly(vinyl-alcohol), titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172), red iron oxide (E172).

What Hesio looks like and contents of the pack

Orange-brown, oblong film-coated tablets scored on both sides with length 18.2 ± 0.3 mm and width 8.2 ± 0.3 mm.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes: 30, 60, 90, 120 or 180 film-coated tablets in PVC/Al blisters in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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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This leaflet was last revised in March 2021.