

Package leaflet: Information for the patient

Herbion Luuderohi, 7mg/ml syrup ivy leaf dry extract *Hederae heliis folii extractum siccum*

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 Herbion Luuderohi is and what it is used for
2. What you need to know before you take Herbion Luuderohi
3. How to take Herbion Luuderohi
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1. What Herbion Luuderohi is and what it is used for

Herbion Luuderohi contains ivy leaf dry extract.

Herbion Luuderohi is a herbal medicinal product used as an expectorant in case of productive cough.

2. What you need to know before you take Herbion Luuderohi

Do not take Herbion Luuderohi:

- if you are allergic to ivy leaf extract, to other plants of the *Araliaceae* (ivy) family or to any of the other ingredients of this medicine (listed in section 6).

Do not give this medicine to children under 2 years of age, because of the risk of worsening of respiratory symptoms associated with cough medicines which work by thinning the mucus in the respiratory tract.

Warnings and precautions

Talk to your doctor or pharmacist before taking Herbion Luuderohi.

- If difficulty in breathing, fever, or purulent (pus containing) sputum occurs, you should consult with your doctor or a pharmacist.
- If the symptoms do not improve after 7 days of the use of the medicine, you should see your doctor.
- It is not recommended that you take this medicine with other medicines that suppress cough (antitussives such as codeine or dextromethorphan) without medical advice.
- If you have stomach problems (gastritis, stomach ulcer), the medicine should be used with caution.

Children

If children between 2–4 years of age have persistent or recurrent cough they require medical diagnosis before treatment.

Other medicines and Herbion Luuderohi

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

Herbion Luuderohi has not been reported to influence the effects of other medicines.

Herbion Luuderohi with food and drink

You may take Herbion Luuderohi regardless of meals.

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.

Herbion Luuderohi is not recommended during pregnancy and breast-feeding due to insufficient data on the use of ivy leaf dry extract in pregnant women and breast-feeding mothers.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed.

Herbion Luuderohi has not been reported to affect the ability to drive and use machines.

Herbion Luuderohi contains sorbitol (E420, sodium benzoate (E211), ethanol and sodium (from sodium benzoate)

5 ml of syrup (1 measuring spoon) contains 1750 mg sorbitol, 10 mg sodium benzoate and 0.5 mg ethanol (a component of lemon balm flavour).

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. You must tell your doctor before receiving this medicine if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea. Sorbitol (≥ 140 mg/kg/day) may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains 0.5 mg of alcohol (ethanol) in 5 ml of syrup (1 measuring spoon). The amount in maximum dose of 15 ml of this medicine is equivalent to less than 0.0375 ml beer or 0.015 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially "sodium-free".

3. How to take Herbion Luuderohi

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for **adults, elderly and adolescents 12 years of age and older** is 5 to 7.5 ml of syrup twice daily.

Use in children

The usual dose for **children 6 to 11 years of age** is 5 ml of syrup twice daily.

The usual dose for **children 2 to 5 years of age** is 2.5 ml of syrup twice daily.

The use in **children under 2 years of age** is contraindicated.

Take the syrup in the morning and in the early afternoon. You may take it regardless of meals.

You should drink plenty of water or other warm caffeine-free beverages while taking Herbion Luuderohi.

If the symptoms persist longer than one week during the use of this product, consult your doctor or pharmacist.

If you take more Herbion Luuderohi than you should

Do not take larger doses than recommended. Intake of doses larger than those recommended (more than twice the daily dose) may cause nausea, vomiting, diarrhoea and agitation. Treatment is symptomatic.

If you forget to take Herbion Luuderohi

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.

Frequency not known (frequency cannot be estimated from available data):

- nausea, vomiting, diarrhoea.
- allergic reaction manifested as hives (urticaria), skin rash and difficulty breathing (dyspnoea).
- severe allergic reaction (anaphylactic reaction), which can manifest as swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing).

If an allergic reaction occurs, stop taking the medicine and talk to your doctor. In case of a severe allergic reaction seek urgent medical advice.

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 Herbion Luuderohi

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.

This medicine does not require any special storage conditions.
The syrup should be used within 3 months after opening the bottle.

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 Herbion Luuderohi contains**

- The active substance is ivy leaf dry extract. 1 ml of syrup contains 7 mg of ivy leaf dry extract (*Hedera helix* L., folium) (5–7.5:1).
Extraction solvent: Ethanol 30% (m/m).
- The other ingredients are liquid (non crystallising) sorbitol (E420), glycerol (E422), sodium benzoate (E211), citric acid monohydrate (E330), lemon balm flavour (contains also ethanol), purified water. See section 2 "Herbion Luuderohi contains sorbitol (E420), sodium benzoate (E211), ethanol and sodium (from sodium benzoate)".

What Herbion Luuderohi looks like and contents of the pack

The syrup is yellow-brown and has a specific odour and taste. A slight sediment can be noticed. The syrup is available in boxes with 150 ml of syrup in a bottle, a measuring spoon is enclosed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
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