

Package leaflet: Information for the patient

Herbion Luuderohi lozenges

Dry extract of ivy leaves

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
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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 in adults, adolescents and children 6 years of age and older.

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.

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

Do not use Herbion Luuderohi lozenges in children under 2 years of age. The use of Herbion Luuderohi lozenges in children 2 to 5 years of age is not recommended since this formulation does not allow for dose adaptation. The use of syrup is recommended in this age group.

Other medicines and Herbion Luuderohi

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

Ivy leaf dry extract has not been reported to influence the effects of other medicines.

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 contains isomalt (E953) and butylhydroxyanisole (E320)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Butylhydroxyanisole (E320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

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** 1 lozenge three times daily.

Use in children

The usual dose for **children 6 to 11 years of age** is 1 lozenge twice daily.

Dissolve the lozenge in the mouth. Do not take the lozenges immediately before or during 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.

Do not store above 25 °C.

Store in the original package 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 Herbion Luuderohi contains

- The active substance is ivy leaf dry extract. Each lozenge contains 35 mg of extract (as dry extract) from *Hedera helix* L., folium (ivy leaf) (5–7.5:1).
Extraction solvent: Ethanol 30% (m/m).
- The other ingredients are isomalt (E953), citric acid (E330), natural flavour caramel (propylene glycol (E1520)), natural flavour citrus (butylhydroxyanisole (E320)), sucralose (E955) and peppermint oil. See section 2 "Herbion Luuderohi contains isomalt (E953) and butylhydroxyanisole (E320)".
- Excipient used in the extract: simethicone.

What Herbion Luuderohi looks like and contents of the pack

The lozenges are round with bevelled edges and a rough surface from light brown to brown colour. Allowed is presence of yellow to brown particles, lighter patches, air bubbles and small, jagged edges. Lozenge diameter: 18.0 mm–19.0 mm, thickness: 7.0 mm–8.0 mm.

The lozenges are available in boxes of 8, 16, 24, 32 and 40 lozenges in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

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

Authorisation Holder:

KRKA, d.d., Novo Mesto Estonian branch
Pärnu mnt 141
11314 Tallinn
Tel. +372 6671658

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