

Package leaflet: Information for the user

Herbion Islandi Käokõrv syrup *cetraria islandica thallus extractum spissum*

For cough relief

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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...14 days.

What is in this leaflet

1. What Herbion Islandi Käokõrv syrup is and what it is used for
2. What you need to know before you use Herbion Islandi Käokõrv syrup
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1. What Herbion Islandi Käokõrv syrup is and what it is used for

Herbion Islandi Käokõrv syrup contains a thick extract of Iceland moss. It is a traditional herbal remedy that is recommended for symptomatic relief of throat irritation in the case of dry cough, and sore mouth and throat.

Indication is based on long-standing application experience.

2. What you need to know before you use Herbion Islandi Käokõrv syrup

Do not use Herbion Islandi Käokõrv syrup

- if you are allergic to Iceland moss extract or any other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Herbion Islandi Käokõrv syrup.

- If you develop breathing difficulties, fever, persistent cough, hoarseness or bloody sputum, consult your doctor or pharmacist.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 to 14 days.

Other medicines and Herbion Islandi Käokõrv syrup

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

There is no data about Herbion Islandi Käokõrv syrup influencing the therapeutic effect of other medicines.

Herbion Islandi Käokõrv syrup with food and drink

It is recommended to regularly drink tea or other hot drinks while being treated with Herbion Islandi Käokõrv syrup, but not right after taking the medicine.

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 for advice before taking this medicine.

Herbion Islandi Käkõrv syrup is not recommended for pregnant or breast-feeding women due to lack of sufficient clinical data concerning the use of Herbion Islandi Käkõrv syrup in pregnant and breast-feeding women.

There are no data available about the effect of the medicine on fertility.

Driving and using machines

The effect of Herbion Islandi Käkõrv syrup on ability to drive or use machines has not been studied.

Herbion Islandi Käkõrv syrup contains sorbitol, ethanol and benzoate

This medicine contains 532 mg sorbitol per ml of syrup.

Sorbitol is a source of fructose. If you have been told by your doctor that you (or your child) have an intolerance to some sugars, or if you (or your child) have been diagnosed with rare hereditary problems of fructose intolerance (which may prevent the body from breaking down fructose), you should consult your doctor before taking this medicine.

Sorbitol may cause gastrointestinal upset and mild diarrhoea.

This medicine contains 0.6 mg of alcohol (ethanol) per ml of syrup.

The alcohol content of one ml of this medicine is less than 1 ml of beer or 1 ml of wine.

The small amount of alcohol in this medicine has no significant effect.

This medicine contains up to 2 mg of benzoate per ml of syrup.

3. How to take Herbion Islandi Käkõrv syrup

Always take Herbion Islandi Käkõrv syrup 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.

The recommended dose for adults and adolescents above 16 years of age is 15 mL of syrup four times daily.

Use in children and adolescents

The recommended dose for children **between 10 and 16 years of age** is 10 mL of syrup four times daily.

The recommended dose for children **between 4 and 10 years of age** is 5 mL of syrup four times daily.

The recommended dose for children **between 1 and 4 years of age** is 2.5 mL of syrup four times daily.

Do not eat or drink right after taking the syrup. However, it is recommended to regularly drink liquids (tea, hot drinks) during the treatment course.

The duration of the treatment depends on the nature and severity of the disease; treatment may last for an extended period of time. It is recommended to keep taking the medicine for a few days after the clinical symptoms have subsided.

Shake the bottle before using the medicine.

If you take more Herbion Islandi Käkõrv syrup than you should

Do not use higher doses than recommended. No data are available with regard to overdose.

If you forget to take Herbion Islandi Käkõrv syrup

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, Herbion Islandi Käökõrv syrup can have side effects, although not everybody gets them.

The side effects are classified into the following groups in order of frequency:

Very common	Occurs in more than 1 user out of 10
Common	Occurs in one to 10 users out of 100
Uncommon	Occurs in 1 to 10 users out of 1000
Rare	Occurs in 1 to 10000 users out of 10,000
Very rare	Occurs in less than 1 user out of 10,000
Not known	Cannot be evaluated based on the available data

Hypersensitivity reactions with unknown frequencies have been observed in patients taking Herbion Islandi Käökõrv syrup. If you develop any allergic reactions, stop taking the medicine and consult a doctor.

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 Islandi Käökõrv syrup

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 after "EXP". The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

The syrup can be used within 3 months after first opening of 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 to protect the environment.

6. Contents of the pack and other information

What Herbion Islandi Käökõrv syrup contains

- The active substance is thick Iceland moss extract. 1 mL of syrup contains 6 mg of thick Iceland moss thallus extract (*Cetraria islandica thallus extractum spissum*), which corresponds to 96-108 mg of Iceland moss.
Extractive agent: water.
- The other ingredients are: sorbitol solution (non-crystallising) (E420), xanthan gum (E415), sodium benzoate (E211), citric acid monohydrate (E330) and lemon flavour (lemon essential oil, ethanol, water, aromatic litsea (*Litsea cubeba*)) and purified water.
See section 2 "Herbion Islandi Käökõrv syrup contains sorbitol, ethanol and benzoate".

What Herbion Islandi Käökõrv syrup looks like and contents of the pack

The syrup is a yellowish-brown to brown, slightly opalescent liquid. It may contain a small amount of residue.

The syrup is available in a cardboard box. The package contains a 150 mL syrup bottle and a measuring

spoon.

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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This leaflet was last revised in October 2019.