Summary of product characteristics

1.3.1	Iceland moss extract
SPC, Labeling and Package Leaflet	AM

1. NAME OF THE MEDICINAL PRODUCT

Herbion® Iceland moss syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of syrup contains 6 mg of Iceland moss soft extract (*Cetraria islandica* (L.) Acharius s.l., *tallus*), which is equivalent to 96 to 108 mg of Iceland moss.
Extraction solvent: water.

Excipients with known effect: sorbitol (E420), ethanol.
1 ml of syrup contains 760 mg sorbitol and 0.6 mg ethanol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

The syrup is a yellow-brown to brown, slightly opalescent liquid with specific odour and taste. Slight sediment typical of natural substances can be noticed.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbion Iceland moss syrup is a herbal medicine that is recommended for:

- dry, irritating cough,
- mild inflammations of the upper respiratory tract and irritation of the oral and pharyngeal mucosa, hoarseness and sore throat.

Iceland moss extract contains high amounts of water-soluble mucilages, which are presumed to cover, protect and moisten the oral and pharyngeal mucosa, thus relieving irritation and dry cough.

Herbion Iceland moss syrup is indicated in adults and children over four years of age.

4.2 Posology and method of administration

Posology
Children 4 to 10 years of age: 5 ml of syrup (one dosing spoon) four times daily.
Children 10 to 16 years of age: 10 ml of syrup (2 dosing spoon) four times daily.
Adults and adolescents over 16 years of age: 15 ml of syrup (3 dosing spoons) four times daily.

Herbion Iceland moss syrup is not suitable for children and infants under four years of age.

Method of administration
Patients should not eat or drink immediately after taking Herbion Iceland moss syrup because the medicine could be removed from the oral and pharyngeal mucosa too soon.

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Drinking plenty of tea or other warm beverages is recommended while taking Herbion Iceland moss syrup, but not immediately after taking the medicine.

The duration of treatment depends on the nature and severity of the disease and treatment may last continuously for a longer period of time (7–14 days). It is recommended that the medicine be taken for a few days after the clinical signs of the disease have disappeared.

Do not exceed the recommended dose.
Shake the bottle before use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Acute peptic ulcer.

4.4 Special warnings and precautions for use

In airway problems accompanied by difficulty breathing, fever, chronic cough or bloody sputum, a doctor should be seen immediately.

If the condition does not improve or get worse after 7 days of treatment, a doctor should be seen.

Herbion iceland moss syrup is intended for use in adults and children aged 4 years or older.

This medicinal product contains sorbitol. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) must not be given this medicine unless strictly necessary. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
This medicine contains small amounts of ethanol (alcohol), less than 100 mg per dose.

4.5 Interaction with other medicinal products and other forms of interaction

Herbion Iceland moss syrup has not been reported to influence the effects of other drugs. No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Since there are limited clinical data on the use of the Iceland moss extract during pregnancy and lactation, the syrup is not recommended for pregnant women and breast-feeding mothers.

4.7 Effects on ability to drive and use machines

There are no data available on the effect of Herbion Iceland moss syrup on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects that may occur during treatment with Herbion Iceland moss syrup are classified into the following groups in order of frequency:
- very common (≥1/10),
- common (≥1/100 to <1/10),

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- uncommon (≥1/1,000 to <1/100),
- rare (≥1/10,000 to <1/1000),
- very rare (<1/10,000),
- not known (cannot be estimated from the available data).

Frequency of undesirable effects listed by individual organ systems:

	Not known
Immune system disorders	Hypersensitivity reaction

In case of allergic reaction treatment should be discontinued and a doctor should be consulted.

Rare case of pruritus, nausea, abdominal pain, hearthburn and burning feeling in the mouth have been reported.

If severe undesirable effects occur, treatment should be discontinued.

4.9 Overdose

Doses larger than recommended should not be taken. No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: cough suppressants, excl. combinations with expectorants, ATC code: R05D.

Herbion Iceland moss syrup is a herbal medicine whose use for dry, irritating cough, hoarseness and sore throat is based solely on long-term experience and pharmacological data. No clinical studies have been performed with the syrup.
The main components of the extract are mucilages with polysaccharides, which are presumed to cover the upper respiratory tract mucosa and form a protective layer, thus supposedly suppressing the cough reflex caused by external stimuli and relieving dry, irritating cough. Mucilages are also presumed to bind water on the mucosa surface and thus moisten irritated and dry oral and pharyngeal mucosa.

5.2 Pharmacokinetic properties

There are no data available on the pharmacokinetic properties of Iceland moss extract.

5.3 Preclinical safety data

Protolichesterinic acid showed no toxic effects in *in vitro* tests on tissue culture of breast cells.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

liquid (non crystallising) sorbitol (E420)
xanthan gum (E415)

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sodium benzoate (E211)
citric acid monohydrate (E330)
lemon flavour (ethanol)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

The syrup should be used within 3 months after opening the bottle.

6.4 Special precautions for storage

Do not refrigerate.

Before opening the bottle:
Do not store above 30°C.

After opening the bottle:
Do not store above 25°C.

6.5. Nature and contents of container

Brown glass bottle, Class III (Ph. Eur.), plastic cap, measuring spoon: 150 ml of syrup, in a box.

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT