1. NAME OF THE MEDICINAL PRODUCT

Herbion® ivy syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hederae helicis folium

1 ml of syrup contains 7 mg of ivy leaf dry extract (*Hedera helix* L., folium) (5–7.5 : 1).
Extraction solvent: 30% (m/m) ethanol.

Excipient(s) with known effect
5 ml of syrup (1 measuring spoon) contains 1750 mg sorbitol (E420) and 0.5 mg ethanol (a component of lemon balm flavour).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.
The syrup is yellow-brown and has a specific odour and taste. A slight sediment can be noticed.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbion ivy syrup is a herbal medicinal product that is used as an expectorant in complex therapy of acute respiratory disease, accompanied by productive cough.

4.2 Posology and method of administration

Adults and adolescents over 12 years of age: 5 to 7.5 ml (one to one and a half measuring spoons) of syrup twice daily (corresponding to 70 to 105 mg of ivy leaf dry extract daily).

Children 6 to 12 years of age: 5 ml (one measuring spoon) of syrup twice daily (corresponding to 70 mg of ivy leaf dry extract daily).

Children 2 to 5 years of age: 2.5 ml (half a measuring spoon) of syrup twice daily (corresponding to 35 mg of ivy leaf dry extract daily).

The use in children under 2 years of age is contraindicated (see section 4.3).

This syrup is intended for oral use. It should be taken in the morning and in the early afternoon.
Drinking plenty of warm beverages is recommended while taking Herbion ivy syrup.
The drug may be taken regardless of meals.

If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted. Treatment duration is then determined by a doctor according to the disease course and individual efficacy and tolerability of therapy.

One measuring spoon contains 5 ml.

Renal and/or hepatic impairment
Patients with renal and/or hepatic impairment should seek medical advice on the recommended dose before taking Herbion ivy syrup.

4.3 Contraindications

Hypersensitivity to the active substance, to other plants of the *Araliaceae* (ivy) family or to any of the excipients.
Children under 2 years of age because of the risk of aggravation of respiratory symptoms.

4.4 Special warnings and precautions for use

Persistent or recurrent cough in children between 2-4 years of age requires medical diagnosis before treatment.

If symptoms do not improve with treatment or if they get worse, i.e., if dyspnoea, fever or purulent sputum occur, a doctor should be consulted.

Concomitant use with antitussives such as codeine or dextromethorphan is not recommended without medical advice.

Caution is recommended in patients with gastritis or gastric ulcer.

Herbion ivy syrup contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.
This medicine contains glycerol, which may cause headache, stomach upset and diarrhoea.
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 ivy syrup has not been reported to influence the effects of other drugs. No interaction studies have been performed.

4.6 Pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Frequency of undesirable effects listed by individual organ systems:

	Common	Uncommon
Immune system disorders		allergic reactions (urticaria, skin rash, couperoses, dyspnoea)
Gastrointestinal disorders	nausea vomiting diarrhoea	

If undesirable effects occur, including those not listed above, treatment should be discontinued and a doctor consulted.

4.9 Overdose

Doses larger than recommended should not be taken. Intake of doses larger than those recommended (more than twice the daily dose) can provoke nausea, vomiting, diarrhoea and agitation. Treatment is symptomatic.

In case of overdose patients should consult their doctor.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cough and cold preparations, Expectorants, excl. combinations with cough suppressants, ATC code: R05CA12.

The mechanism of action is not known.
The principal ingredients of ivy leaf dry extract are triterpene saponins, mainly hederacoside C and alpha hederin.

5.2 Pharmacokinetic properties

There are no data available on the pharmacokinetic properties of ivy leaf dry extract.

5.3 Preclinical safety data

α-Hederin, ß-hederin and δ-hederin isolated from ivy leaf showed no mutagenic potential in the Ames test using *Salmonella typhimurium* strain TA 98, with or without S9 activation.
Data on genotoxicity, carcinogenicity and reproductive toxicity testing for ivy leaf preparations are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

sorbitol, liquid (non crystallising) (E420)

glycerol (E422)
sodium benzoate (E211)
citric acid (E330)
lemon balm flavour: propylene glycol (E1520), ethanol (E1520), citronella oil, lemon oil, citral ex. Litsea cubeba, coriander oil
water, purified

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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Glass bottle, plastic cap, measuring spoon: 150 ml of syrup, in a box.

6.6 Special precautions for disposal

No special 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