1.3.1	Ivy leaf dry extract
SPC, Labeling and Package Leaflet	AM

1. NAME OF THE MEDICINAL PRODUCT

Herbion ivy lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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).

Excipients with known effect
Each lozenge contains 2447.50 mg isomalt (E953) and 0.0006 mg butylhydroxyanisole (E320).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbion ivy is a herbal medicinal product used as an expectorant in complex treatment of acute respiratory diseases accompanied by productive cough.

4.2 Posology and method of administration

Posology
Adults, elderly and adolescents 12 years of age and older: 1 lozenge three times daily (corresponding to 105 mg of ivy leaf dry extract daily).

Paediatric population
Children 6 to 11 years of age: 1 lozenge twice daily (corresponding to 70 mg of ivy leaf dry extract daily).

For children **2 to 5 years of age** no adjusted dosage is possible with the lozenge formulation. The use of a syrup formulation is recommended in this age group.

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

If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted. Further duration of treatment is determined by the doctor, taking into account the characteristics of the disease, the achieved effect and the tolerability of the medicinal product.

Renal and/or hepatic impairment

Patients with renal and/or hepatic impairment should seek medical advice before starting treatment.

Method of administration
Oromucosal use.
Dissolve the lozenge in the mouth.

Drinking plenty of water or other warm caffeine-free beverages is recommended. The lozenges should not be taken immediately before or during meals.

4.3 Contraindications

Hypersensitivity to the active substance, to other plants of the *Araliaceae* (ivy) family or to any of the excipients listed in section 6.1.
Children under 2 years of age because of the general risk of aggravation of respiratory symptoms through secretolytic drugs.

4.4 Special warnings and precautions for use

If symptoms persist or get worse during treatment, and when dyspnoea, fever or purulent sputum occurs, 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.

Isomalt (E953)
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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

4.5 Interaction with other medicinal products and other forms of interaction

There is no data on interactions with other medicinal products.

4.6 Fertility, pregnancy and lactation

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

Breast-feeding
Safety during lactation has not been established. In the absence of sufficient data, the use during 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 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:

	Frequency not known
Immune system disorders	allergic reactions (urticaria, skin rash, dyspnoea, anaphylactic reaction)
Gastrointestinal disorders	nausea, vomiting, diarrhoea

If severe undesirable effects occur, treatment should be discontinued.

4.9 Overdose

Intake of doses larger than those recommended (more than twice the daily dose) can provoke nausea, vomiting, diarrhoea and agitation. Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Herbion ivy lozenges contain ivy leaf dry extract; its main components are triterpene saponins.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Ivy leaf dry extract was not mutagenic in Ames test with *S.* typhimurium strains TA 97a, TA 98, TA 100, TA 1535 and TA 102 with or without metabolic activation. Data on carcinogenicity and reproductive toxicity testing for ivy leaf preparations are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isomalt (E953)
Citric acid (E330)
Natural flavour caramel (propylene glycol (E1520))
Natural flavour citrus (butylhydroxyanisole (E320))

Sucralose (E955)
Peppermint oil

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister (PVC/PE/PVDC//Alu): 16 and 32 lozenges, in a box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

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