

1.3 PRODUCT INFORMATION

1.3.1 SPC

SPC of Mucoplant cough syrup ivy¹, please see attachment.

¹ Mucoplant cough syrup ivy (During the DCP the dosage form following Mucoplant is mentioned as "cough syrup ivy" in the texts of Modul 1.3.1 and 1.3.2. The appropriate relevant national translations of the dosage form are presented in Annex 5.19 of Module 1.2 and will be considered in the national procedure of the DCP.)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Mucoplant cough syrup ivy
Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml of syrup contain 154 mg of ivy leaf dry extract (*Hedera helix* L. folium) (4 – 8 : 1).
Extraction solvent: Ethanol 30 % (m/m).

Excipient with known effect: 1 ml of the drug product contains 400 mg maltitol, liquid.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup
Brownish-yellow, slightly turbid syrup with characteristic odour (currant).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mucoplant cough syrup ivy is an herbal medicinal product used as an expectorant in case of productive cough for adults, adolescents and children from 2 years of age.

4.2 Posology and method of administration

Posology

Adult, adolescents and children over 12 years of age:

20 ml (2x 10 ml) three times a day (corresponding to **92.40** mg of ivy leaf dry extract daily)

Children between 6-12 years of age:

15 ml three times a day (corresponding to **69.30** mg of ivy leaf dry extract daily)

Children between 2-5 years of age:

7.5 ml three times a day (corresponding to **34.65** mg of ivy leaf dry extract daily)

For correct dosage the enclosed measuring cup is to be used.

Mucoplant cough syrup ivy is contraindicated in children under 2 years of age (see section 4.3).

Patients with renal and/or hepatic impairment:

Due to the lack of data in these patients groups, a dose recommendation is not possible. Patients are advised to consult their doctor or pharmacist before taking Mucoplant cough syrup ivy.

Method of administration

Oral use.

Mucoplant cough syrup ivy should be taken undiluted and drinking plenty of water or warm caffeine-free beverages is recommended.

If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance, to 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 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.

When dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist 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.

Mucoplant cough syrup ivy contains maltitol, liquid:

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

10 ml syrup contain 4 g maltitol, liquid corresponding to about 0.3 bread units. This has to be considered important for people suffering from diabetes mellitus. The calorie value is 2.3 kcal/g maltitol, liquid.

Maltitol, liquid may have a mild laxative effect.

4.5 Interaction with other medicinal products and other forms of interaction

Mucoplant cough syrup ivy has not been reported to influence the effects of other drugs. No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Ivy leaf dry extract in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Mucoplant cough syrup ivy is not recommended during pregnancy.

Breast-feeding

It is unknown whether constituents or metabolites of Ivy leaf dry extract are excreted in human breast milk. A risk to the newborns/infants cannot be excluded. Mucoplant cough syrup ivy should not be used during breast-feeding.

Fertility

There are no data on the effects of Ivy leaf dry extract on fertility available.

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. Mucoplant cough syrup ivy has not been reported to affect the ability to drive and use machines.

4.8 Undesirable effects

The assessment of the adverse events is in accordance to the following frequency convention:

very common ($\geq 1/10$),
common ($\geq 1/100$ to $< 1/10$),
uncommon ($\geq 1/1,000$ to $< 1/100$),
rare ($\geq 1/10,000$ to $< 1/1,000$),
very rare ($< 1/10,000$),
not known (cannot be estimated from the available data).

Common: Gastrointestinal disorders: nausea, vomiting, diarrhoea.

Uncommon: Immune system disorders: Allergic reactions of the skin (urticaria, skin rash, couperoses) and systemic allergic reactions as dyspnoea and Quinke-edema.

If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Overdose can provoke nausea, vomiting, diarrhoea and agitation. Treatment is symptomatic. One case of a 4 year old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding to 1.8 g herbal substance, (equivalent to 195 ml of Mucoplant cough syrup ivy) has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Respiratory system, expectorants, excl. combinations with cough suppressants

ATC code: R05C

The mechanism of action is not known.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Preclinical data are incomplete and therefore of limited informative value. Based on the long standing clinical use there is a sufficiently established safety of the usage in the given posology in humans. An Ames-Test on mutagenicity does not give any reason for concern for the herbal preparation. Tests on reproductive toxicity and carcinogenicity do not exist.

6. PHARMACEUTICAL PARTICULARS

Brownish-yellow, slightly turbid syrup with characteristic odour (currant).

6.1 List of excipients

Potassium sorbate
Hydroxyethyl cellulose
Flavour, black currant
Maltitol, liquid (E 965)
Citric acid anhydrous
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months for the package size of 100 ml.
18 months for the package size of 200 ml and 250 ml.

Mucoplant cough syrup ivy can be used 6 weeks after opening the bottle.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Brown glass bottle with pourer (LDPE), plastic screw-cap (HDPE or PP), measuring cup (PP) with graduations of 2.5, 5, 7.5, 10, and 15 ml.
Bottles of 100 ml, 200 ml, 250 ml volume are available.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dr. Theiss Naturwaren GmbH
Michelinstraße 10
66424 Homburg
Germany

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]