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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Hedera helix* L., folium

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Community herbal monograph on *Hedera helix* L., folium

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[1,2]

Well-established use	Traditional use
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended
Hedera helix L., folium (ivy leaf)	*Hedera helix* L., folium (ivy leaf)
i) Herbal substance	i) Herbal substance
Not applicable.	Not applicable.
ii) Herbal preparations	ii) Herbal preparations
a) Dry extract (DER 4-8:1), extraction solvent ethanol 24-30% m/m	a) Soft extract (DER 2.2-2.9:1), extraction solvent ethanol 50% V/V: propylene glycol (98:2)
b) Dry extract (DER 6-7:1), extraction solvent ethanol 40% m/m	
c) Dry extract (DER 3-6:1), extraction solvent ethanol 60% m/m	
d) Liquid extract (DER 1:1), extraction solvent ethanol 70% V/V	

3. Pharmaceutical form

Well-established use	Traditional use
Herbal preparations in solid or liquid dosage forms for oral use.	Herbal preparations in solid or liquid dosage forms for oral use.
The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:2148).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product used as an expectorant in case of productive cough.	Traditional herbal medicinal product used as an expectorant in cough associated with cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
Posology *Adolescents, adults and elderly* a) Single dose: 15-65 mg, one to three times daily up to a daily dose of 45-105 mg. (Note: Maximum daily dose for ethanol-containing finished products: 67 mg; corresponding to 420 mg herbal substance). b) Single dose: 14-18 mg, three times daily. c) Single dose: 33 mg, two times daily. d) Single dose: 100 mg, three times daily. *Children between 6-12 years of age* a) Single dose: 11-33 mg, two to three times daily up to a daily dose of 33-70 mg. (Note: Maximum daily dose for ethanol-containing finished products: 34 mg; corresponding to 210 mg herbal substance). b) Single dose: 9-18 mg, two to three times daily up to a daily dose of 15-40 mg Daily dose: 15-40 mg. c) Single dose: 25 mg, two times daily. d) Single dose: 75 mg, three times daily. *Children between 2-5 years of age* a) Single dose: 8-18 mg, two to three times daily up to a daily dose of 24-36 mg. (Note: Maximum daily dose for ethanol-containing finished products: 24 mg; corresponding to 150 mg herbal substance).	**Posology** *Adolescents, adults and elderly* a) Single dose: 40 mg, three times daily. *Children between 5-12 years of age* a) Single dose: 20-26 mg, three to four times daily up to a maximum daily dose of 80 mg. *Children of 4 years of age* a) Single dose: 20 mg, three times daily. The use in children between 2-4 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). The use in children under 2 years of age is contraindicated (see section 4.3 'Contraindications'). **Duration of use** If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

Well-established use	Traditional use
b) Single dose: 7-9 mg, two to three times daily up to a daily dose of 17-27 mg. c) Single dose: 17 mg, two times daily. The use in children under 2 years of age is contraindicated (see section 4.3 'Contraindications'). **Duration of use** If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted. **Method of administration** Oral use.	

4.3. Contraindications

Well-established use	Traditional use
Hypersensitivity to the active substance or to plants of the Araliaceae family. Children under 2 years of age because of the risk of aggravation of respiratory symptoms.	Hypersensitivity to the active substance or to plants of the Araliaceae family. Children under 2 years of age because of the risk of aggravation of respiratory symptoms.

4.4. Special warnings and precautions for use

Well-established use	Traditional 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 dextromethorphane is not recommended without medical advice. Caution is recommended in patients with gastritis or gastric ulcer. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included. Preparation d) should not be administered to	The use in children between 2-4 years of age is not recommended because medical advice should be sought. When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted. Concomitant use with antitussives such as codeine or dextromethorphane is not recommended without medical advice. Caution is recommended in patients with gastritis or gastric ulcer. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

Well-established use	Traditional use
children under 6 years of age because of the alcohol content.	

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
None reported.	None reported.

4.6. Pregnancy and lactation

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

Well-established use	Traditional use
No studies on the effect on the ability to drive and use machines have been performed.	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
Common: gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. Uncommon: allergic reactions (urticaria, skin rash, couperoses, dyspnoea) have been reported. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	Allergic reactions (urticaria, skin rash, couperoses, dyspnoea) and gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
Overdose can provoke nausea, vomiting, diarrhoea and agitation. One case of a 4-year old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding 1.8 g herbal	Overdose can provoke nausea, vomiting, diarrhoea and agitation. One case of a 4-year old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding 1.8 g herbal

Well-established use	Traditional use
substance has been reported.	substance has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: respiratory system Proposed ATC code: RO5 C The mechanism of action is not known.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
No data available.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
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.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. 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

Well-established use	Traditional use
Not applicable.	Not applicable.

7. Date of compilation / last revision

31 March 2011