28 January 2015
EMA/HMPC/586888/2014
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Hedera helix* L., folium

Draft revision

Initial assessment	
Discussion in Working Party on Community monographs and Community list (MLWP)	May 2009 November 2009 January 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 January 2010
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 June 2010
Rediscussion in MLWP	September 2010 November 2010 January 2011 March 2011
Adoption by HMPC Monograph (EMEA/HMPC/289430/2009) AR (EMEA/HMPC/289432/2009) List of references (EMEA/289429/2009)	31 March 2011
First revision	
Discussion in MLWP	September 2014 November 2014 January 2015
Adoption by HMPC for release for consultation	28 January 2015
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 May 2015
Rediscussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; well-established medicinal use; traditional use; *Hedera helix* L., folium; Hederae helicis folium; ivy leaf

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

BG (bălgarski): Бръшлян, лист CS (čeština): Břečťanový list DA (dansk): Vedbendblad DE (Deutsch): Efeublätter EL (elliniká): Φύλλο κισσού EN (English): ivy leaf ES (espanol): Hiedra, hoja de ET (eesti keel): Luuderohuleht FI (suomi): muratti, lehti FR (français): Lierre (feuille de) HR (hrvatska): Bršljanov list HU (magyar): Borostyánlevél IT (italiano): Edera foglia	LT (lietuvių kalba): Gebenių lapai LV (latviešu valoda): Vijīgās efejas lapas MT (malti): Werqa tal-Liedna NL (nederlands): Klimop PL (polski): Liść bluszczu PT (português): Hera, folha RO (română): Frunză de iederă SK (slovenčina): Brečtanový list SL (slovenščina): List navadnega bršljana SV (svenska): Murgröneblad *IS (íslenska)*: *NO (norsk):* Eføyblad

European Union 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 *Hedera helix* L., folium (ivy leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Dry extract (DER 4-8:1), extraction solvent ethanol 24-30% m/m 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 e) Soft extract (DER 2.2-2.9:1), extraction solvent ethanol 50% v/v: propylene glycol (98:2)	

3. Pharmaceutical form

Well-established use	Traditional 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.	

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.	

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 Daily dose: 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. e) Single dose: 40 mg, three times daily. *Children between 6-11 years of age* a) Single dose: 11-33 mg, two to three times daily Daily dose: 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 dose: 15-40 mg. c) Single dose: 25 mg, two times daily. d) Single dose: 75 mg, three times daily. e) Single dose: 20-26 mg, three to four times daily Daily dose: maximum 80 mg. *Children between 2-5 years of age* a) Single dose: 8-18 mg, two to three times daily	

Well-established use	Traditional use
Daily dose: 24-36 mg. (Note: Maximum daily dose for ethanol-containing finished products: 24 mg; corresponding to 150 mg herbal substance). b) Single dose: 7-9 mg, two to three times daily Daily dose: 17-27 mg. c) Single dose: 17 mg, two times daily. e) Single dose: 20 mg, three 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.	

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 opiate antitussives such as codeine or dextromethorphane is not recommended without medical advice. Caution is recommended in patients with gastritis or gastric ulcer.	

Well-established use	Traditional use
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 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.	

4.6. Fertility, 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.	

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.	

4.8. Undesirable effects

Well-established use	Traditional use
Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known. Allergic reactions (urticaria, skin rash, dyspnoea) have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist 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 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.	

5.2. Pharmacokinetic properties

Well-established use	Traditional use
No data available.	

5.3. Preclinical safety data

Well-established use	Traditional use
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.	

7. Date of compilation / last revision

28 January 2015