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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS  
(HMPC)**

**DRAFT**

**COMMUNITY HERBAL MONOGRAPH ON *HEDERA HELIX* L., FOLIUM**

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| <b>DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b>   | 12 May 2009<br>November 2009<br>January 2010 |
| <b>ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION</b>                                   | 14 January 2010                              |
| <b>END OF CONSULTATION (DEADLINE FOR COMMENTS)</b>                                     | 15 June 2010                                 |
| <b>REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)</b> |  |
| <b>ADOPTION BY HMPC</b>  |  |

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Fax: +44 20 75 23 70 51

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| <b>KEYWORDS</b> | Herbal medicinal products; HMPC; Community herbal monographs; well-established medicinal use; traditional use; <i>Hedera helix</i> L.; <i>Hederae helicis folium</i> ; ivy leaf |
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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<sup>1 2</sup>

| <u>Well-established use</u>  | <u>Traditional use</u>   |
|--|--|
| 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 |
| <i>Hedera helix</i> L., folium (ivy leaf)  | <i>Hedera helix</i> L., folium (ivy leaf)  |
| i) Herbal substance<br>Not applicable  | i) Herbal substance<br>Not applicable  |
| ii) Herbal preparations  | ii) Herbal preparations  |
| A) dry extract (DER 4-8:1), extraction solvent ethanol 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  | B) liquid extract (DER 1:1), extraction solvent ethanol 70 % V/V                                 |
| C) dry extract (DER 3-6:1), extraction solvent ethanol 60 % m/m  |  |

### 3. PHARMACEUTICAL FORM

| <u>Well-established use</u>   | <u>Traditional use</u>  |
|---|---|
| Herbal preparation in solid or liquid dosage forms for oral use.                              | Herbal preparation 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. |

<sup>1</sup> The material complies with the Eur. Ph. monograph (ref.: 01/2008:2148).

<sup>2</sup> 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

| <u>Well-established use</u>   | <u>Traditional use</u>   |
|---|--|
| Herbal medicinal product used as an expectorant in case of productive cough | Herbal medicinal product traditionally used in common cold.<br><br>The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use. |

### 4.2. Posology and method of administration

| <u>Well-established use</u>  | <u>Traditional use</u>   |
|--|--|
| <b>Posology</b><br><br><i>Adolescents, adults and elderly</i><br><br>Herbal preparation A:<br>Single dose: 15-65 mg<br>Average daily dose: 45-105 mg<br><br>Herbal preparation B:<br>Single dose: 14-18 mg<br>Average daily dose: 42-54 mg<br><br>Herbal preparation C:<br>Single dose: 33 mg<br>Average daily dose: 66 mg<br><br><i>Children between 6-12 years of age</i><br>Herbal preparation A:<br>Single dose: 11-33 mg<br>Average daily dose: 33-70 mg<br><br>Herbal preparation B:<br>Single dose: 9-18 mg<br>Average daily dose: 15-40 mg<br><br>Herbal preparation C:<br>Single dose: 25 mg<br>Average daily dose: 50 mg<br><br><i>Children between 4-5 years of age</i><br>Herbal preparation A:<br>Single dose: 8-18 mg<br>Average daily dose: 25-35 mg<br><br>Herbal preparation B:<br>Single dose: 7-9 mg<br>Average daily dose: 17-27 | <b>Posology</b><br><br><i>Adolescents, adults and elderly</i><br><br>Herbal preparation A:<br>Single dose: 40 mg<br>Average daily dose: 120 mg<br><br>Herbal preparation B:<br>Single dose: 100 mg<br>Average daily dose: 300 mg<br><br>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br><br><b>Duration of use</b><br><br>Not to be used for more than 2 weeks.<br><br>If the symptoms persist longer than a week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br><b>Method of administration</b><br><br>Oral use. |

|  |  |
|--|--|
| <p>Herbal preparation C:<br/>Single dose: 17 mg<br/>Average daily dose: 33 mg</p> <p>The use in children under 4 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p> <p><b>Duration of use</b></p> <p>The medicinal product should not be used longer than 4-5 days without medical advice.</p> <p>If the symptoms do not improve during the use of the medicinal product, a doctor or a pharmacist should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use.</p> |  |
|--|--|

### 4.3. Contraindications

|   |  |
|---|--|
| <p><u>Well-established use</u></p> <p>Hypersensitivity to the active substance or to plants of the Araliaceae family.</p> | <p><u>Traditional use</u></p> <p>Hypersensitivity to the active substance or to plants of the Araliaceae family.</p> |
|---|--|

### 4.4. Special warnings and precautions for use

|   |   |
|---|---|
| <p><u>Well-established use</u></p> <p>The use is not recommended in children below 4 years of age due to insufficient data.</p> <p>The use in children below one year of age may cause vomiting and diarrhoea.</p> <p>Concomitant use with antitussives as codeine or dextromethorphan is not recommended without medical advice.</p> <p>Caution is recommended in patients with gastritis or gastric ulcer.</p> <p>If dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.</p> | <p><u>Traditional use</u></p> <p>The use in children under 12 years of age is not recommended due to lack of adequate data.</p> <p>Concomitant use with antitussives as codeine or dextromethorphan is not recommended without medical advice.</p> <p>Caution is recommended in patients with gastritis or gastric ulcer.</p> <p>If dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.</p> <p>For tinctures 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.</p> |
|---|---|

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

| <u>Well-established use</u> | <u>Traditional use</u> |
|-----------------------------|------------------------|
| None reported.              | None reported.         |

#### 4.6. Pregnancy and lactation

| <u>Well-established use</u>  | <u>Traditional use</u>   |
|--|--|
| Safety during pregnancy and lactation has not been established. The use during pregnancy and lactation is not recommended. | Safety during pregnancy and lactation has not been established. The use during pregnancy and lactation is not recommended. |

#### 4.7. Effects on ability to drive and use machines

| <u>Well-established use</u>  | <u>Traditional use</u>   |
|--|--|
| 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

| <u>Well-established use</u>  | <u>Traditional use</u>   |
|--|--|
| Common - Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported.<br>Uncommon - Allergic reactions (urticaria, skin rash, tuberoses, dyspnoea) can occur.<br><br>If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted. | Allergic reactions (urticaria, skin rash, tuberoses, dyspnoea) and gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known.<br><br>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted. |

#### 4.9. Overdose

| <u>Well-established use</u>  | <u>Traditional use</u>   |
|--|--|
| Overdose can provoke nausea, vomiting, diarrhoea and agitation.<br><br>A 4 year old child developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding 1.8 g herbal substance. | Overdose can provoke nausea, vomiting, diarrhoea and agitation.<br><br>A 4 year old child developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding 1.8 g herbal substance. |

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

| <u>Well-established use</u>   | <u>Traditional use</u>   |
|---|--|
| Pharmacotherapeutic group: respiratory system<br>ATC code: RO5<br><br>Anti-inflammatory actions have been reported. | Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended. |

### 5.2. Pharmacokinetic properties

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

### 5.3. Preclinical safety data

| <u>Well-established use</u>   | <u>Traditional use</u>  |
|---|---|
| $\alpha$ -Hederin, $\beta$ -hederin and $\delta$ -hederin isolated from ivy leaf showed no mutagenic potential in the Ames test using <i>Salmonella typhimurium</i> strain TA 98, with or without S9 activation. These three saponins showed dose-dependent antimutagenic effects against benz(a)pyrene at levels between 80 and 200 $\mu\text{g}/\text{plate}$ in the Ames test.<br><br>Data on carcinogenicity, genotoxicity and reproductive toxicity testing 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.<br><br>Data on carcinogenicity, genotoxicity and reproductive toxicity testing are not available. |

## 6. PHARMACEUTICAL PARTICULARS

| <u>Well-established use</u> | <u>Traditional use</u> |
|-----------------------------|------------------------|
| Not applicable              | Not applicable.        |

## 7. DATE OF COMPILATION/LAST REVISION

14 January 2010