



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

DRAFT

**COMMUNITY HERBAL MONOGRAPH ON
PRIMULA VERIS L., *PRIMULA ELATIOR* (L.) HILL, FLOS**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	8 March 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 June 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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Fax: +44 20 75 23 70 51

KEYWORDS

Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Primula veris* L.; *Primula elatior* (L.) Hill; Primulae flos; primula flower.

**COMMUNITY HERBAL MONOGRAPH ON
PRIMULA VERIS L., *PRIMULA ELATIOR* (L.) HILL, FLOS**

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION¹

<u>Well-established use</u>	<u>Traditional use</u>
<p>With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended</p>	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Primula veris</i> L. and/or <i>Primula elatior</i> (L.) Hill, flos (primula flower)</p> <p>i) Herbal substance Whole or cut, dried flowers</p> <p>ii) Herbal preparations - Liquid extract (1:1, 25% ethanol) - Comminuted herbal substance</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal substance or comminuted herbal substance for tea preparation or other herbal preparation in liquid and solid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p>The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4.2 Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>												
	<p>Posology</p> <p><i>Adolescents over 12 years of age, adults, elderly</i></p> <table data-bbox="818 421 1394 658"> <thead> <tr> <th></th> <th><i>single dose</i></th> <th><i>daily dose</i></th> </tr> </thead> <tbody> <tr> <td>Herbal substance for tea preparation</td> <td>1 g</td> <td>2-4 g</td> </tr> <tr> <td>Comminuted herbal substance for tea preparation</td> <td>1 g</td> <td>2-4 g</td> </tr> <tr> <td>Liquid extract</td> <td>1-3 ml</td> <td>3-6 ml</td> </tr> </tbody> </table> <p>Dosage frequency: 3 times daily</p> <p>The use is not recommended in children under 12 years of age (see 4.4 Special warnings and precautions for use).</p> <p>Duration of use</p> <p><i>Adolescents over 12 years of age, adults, elderly</i> Medical attention should be sought if after 1 week of treatment the symptoms do not improve.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use</p> <p>Tea preparation: 1 g of herbal substance or comminuted herbal substance for infusion. As an expectorant one cup of tea up to 3 times daily.</p>		<i>single dose</i>	<i>daily dose</i>	Herbal substance for tea preparation	1 g	2-4 g	Comminuted herbal substance for tea preparation	1 g	2-4 g	Liquid extract	1-3 ml	3-6 ml
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Liquid extract	1-3 ml	3-6 ml											

4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Hypersensitivity to the active substance or to other Primula species. Children with a history of acute stenosing laryngo-tracheitis. Asthma.</p>

4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	<p>The use is not recommended in children under 12 years of age because no data are available.</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 qualified health care practitioner should be consulted.</p> <p>For extracts, 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.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Safety during pregnancy and lactation has not been established. No adverse effects have been reported from the use of Primula flower as a medicinal product during pregnancy and lactation. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

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.

4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Gastric disorders, nausea, vomiting and allergic reactions may occur. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
	Overdose may lead to stomach upset, vomiting or diarrhoea.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	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>
	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>
	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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

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

7. DATE OF COMPILATION/LAST REVISION

8 March 2007