



This document was valid from September 2007 until September 2012. It is now superseded by a [new version](#) adopted by the HMPC on 24 September 2012 and published on the EMA website.

London, 7 September 2007
Doc. Ref. EMEA/HMPC/64684/2007

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

FINAL

**COMMUNITY HERBAL MONOGRAPH ON *PRIMULA VERIS* L. AND
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)	September 2007
ADOPTION BY HMPC	7 September 2007

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. AND
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>
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	<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, extraction solvent ethanol 25% (V/V)) - Comminuted herbal substance for tea preparation</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</p>

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

	product for use in specified indication exclusively based upon long-standing use.
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4.2 Posology and method of administration

<p><u>Well-established use</u></p>	<p><u>Traditional use</u></p> <p>Posology</p> <p><i>Adolescents over 12 years of age, adults, elderly</i></p> <table border="0"> <thead> <tr> <th></th> <th style="text-align: center;"><i>single dose</i></th> <th style="text-align: center;"><i>daily dose</i></th> </tr> </thead> <tbody> <tr> <td>Herbal substance for tea preparation</td> <td style="text-align: center;">1 g</td> <td style="text-align: center;">2-4 g</td> </tr> <tr> <td>Comminuted herbal substance for tea preparation</td> <td style="text-align: center;">1 g</td> <td style="text-align: center;">2-4 g</td> </tr> <tr> <td>Liquid extract</td> <td style="text-align: center;">1-3 ml</td> <td style="text-align: center;">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
	<i>single dose</i>	<i>daily dose</i>											
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Liquid extract	1-3 ml	3-6 ml											

4.3. Contraindications

<p><u>Well-established use</u></p>	<p><u>Traditional use</u></p> <p>Hypersensitivity to the active substance or to other Primula species. Children with a history of acute obstructive laryngitis. Asthma.</p>
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> The use is not recommended in children under 12 years of age because no data on safety are available. Caution is recommended in patients with gastritis or gastric ulcer. If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted. 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.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> 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.
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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.
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4.8. Undesirable effects

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

7 September 2007