



19 September 2012
EMA/HMPC/136582/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Primula veris* L. and/or *Primula elatior* (L.) Hill, flos

Final

Initial assessment	
Discussion in Working Party on Community monographs and Community list (MLWP)	March 2007
Adoption by Committee on Herbal Medicinal Products (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 Committee on Herbal Medicinal Products (HMPC) Monograph (EMA/HMPC/64684/2007) AR (EMA/HMPC/64683/2007) List of references (EMA/HMPC/111633/2007) Overview of comments received during the public consultation (EMA/HMPC/373075/2007) HMPC Opinion (EMA/HMPC/405544/2007)	7 September 2007
First systematic review	
Discussion in Working Party on Community monographs and Community list (MLWP)	March 2012 May 2012
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	N/A
End of consultation (deadline for comments)	N/A
Rediscussion in Working Party on Community monographs and Community list (MLWP)	N/A
Adoption by Committee on Herbal Medicinal Products (HMPC)	19 September 2012

A search for the versions adopted in September 2007 can be made via the EMA document search function, using the documents' reference number, at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=



Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Primula veris</i> L., <i>Primula elatior</i> (L.) Hill, flos; Primulae flos; Primula flower
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<p>BG (bългарски): Иглика, цвят CS (čeština): Prvosienkový květ DA (dansk): Primulablomst DE (Deutsch): Schlüsselblumenblüten EL (elliniká): Άνθος πριμούλης EN (English): Primula flower ES (español): Prímula, flor de ET (eesti keel): Nurmenukuõis FI (suomi): Kevätesikko, kukka FR (français): Primevère (fleur de) HU (magyar): Kankalinvirág IT (italiano): Primula (Primavera, Primula odorosa) fiore</p>	<p>LT (lietuvių kalba): LV (latviešu valoda): Pīmulu ziedi MT (malti): NL (nederlands): Sleutelbloem PL (polski): Kwiat pierwiosnka PT (português): Primavera, flor RO (română): Floare de ciuboțica cucului SK (slovenčina): Prvosienkový kvet SL (slovenščina): Cvet jegliča SV (svenska): Gullviveblomma IS (íslenska): NO (norsk): Primulablomst</p>
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Community herbal monograph on *Primula veris* L. and/or *Primula elatior* (L.) Hill, flos

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
	<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</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>A) Liquid extract (DER 1:1), extraction solvent ethanol 25% v/v</p> <p>B) Comminuted herbal substance</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Other herbal preparations in liquid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

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

² The material complies with the Deutscher Arzneimittel Codex (DAC 2006).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<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 the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults, elderly</i></p> <p>Herbal preparations:</p> <p>A) Liquid extract: Single dose: 1-3 ml, up to 3 times daily Maximum daily dose 6 ml</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>B) Comminuted herbal substance</p> <p>Herbal tea: 1 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3 times daily.</p> <p>Duration of use</p> <p>If the symptoms persist longer than 1 week 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>

³ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other <i>Primula</i> species.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</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 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

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

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
	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.

4.9. Overdose

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

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	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
	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
	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

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

19 September 2012