EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2012
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Committee on Herbal Medicinal Products (HMPC)

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

Final

Initial assessment	
Discussion in Working Party on Community monographs and Community list (MLWP)	January 2007 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 (EMEA/HMPC/143370/2006) AR (EMEA/HMPC/144474/2006) List of references (EMEA/HMPC/111736/2007) Overview of comments received during the public consultation (EMEA/HMPC/373077/2007) HMPC Opinion (EMEA/HMPC/405542/2007)	7 September 2007
First systematic review	
Discussion in Working Party on Community monographs and Community list (MLWP)	January 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=

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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Primula veris* L., *Primula elatior* (L.) Hill, radix; Primulae radix; Primula root

BG (bălgarski): Иглика, корен CS (čeština): Prvosenkový kořen DA (dansk): Primularod DE (Deutsch): Primelwurzel EL (elliniká): Ρἰζα πριμοὐλης EN (English): Primula root ES (espanol): Prímula, raíz de ET (eesti keel): Nurmenukujuur FI (suomi): Kevätesikko, juuri FR (français): Primevère (racine de) HU (magyar): Kankalingyökér IT (italiano): Primula (Primavera, Primula odorosa) radice	LT (lietuvių kalba): LV (latviešu valoda): Prīmulu saknes MT (malti): Għerq tal-Primula NL (nederlands): Sleutelbloem PL (polski): Korzeń pierwiosnka PT (português): Primavera, raiz RO (română): Rădăcină de ciuboţica cucului SK (slovenčina): Prvosienkový koreň SL (slovenščina): Korenina jegliča SV (svenska): Gullviverot *IS (íslenska)*: *NO (norsk):* Primularot

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

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 registration application of Article 16d(1) of Directive 2001/83/EC as amended *Primula veris* L. and/or *Primula elatior* (L.) Hill, radix (Primula root) i) Herbal substance Not applicable ii) Herbal preparations A) Dry extract (DER 3-9:1), extraction solvent ethanol 40-50 % v/v B) Liquid extract (DER 1:1), extraction solvent ethanol 70 % v/v C) Liquid extract (DER 1:2.0-2.5), extraction solvent ethanol 70% v/v D) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70 % v/v E) Soft extract (DER 5-10:1), extraction solvent water F) Soft extract (DER 1-4:1), extraction solvent ethanol 20-55% v/v G) Soft extract (DER 6-10:1), extraction solvent methanol, water, ammonia solution 10% (50.0:49.5:0.5) H) Soft extract (DER 6-10:1), extraction solvent methanol 50% I) Comminuted herbal substance

[1] The material complies with the Eur. Ph. monograph (ref. 01/2008:1364 corrected 6.0)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with the relevant herbal quality guidance.

3. Pharmaceutical form

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

4. Clinical particulars

4.1. Therapeutic indications

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

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adolescents, adults, elderly* Herbal preparations A (according to ÖAB[4]), B, C, D, G: A) Dry extract (according to ÖAB with DER 3-3.5:1): Single dose: 0.1 – 0.2 g, 3 times daily B) Liquid extract: Single dose: 0.5 g, 3 times daily C) Liquid extract: Single dose: 0.6 g, 4 times daily D) Tincture: Single dose: 0.5 – 1 g, 3 times daily G) Soft extract:

[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] Austrian pharmacopoeia (current edition)

Well-established use	Traditional use
	Single dose: 22.5 mg, 3 times daily Herbal preparations A (different DER to ÖAB), E, F, H: Single dose equivalent to 0.2 – 0.5 g herbal substance (depending on the actual DER), 3 times daily Herbal preparation I: Herbal tea: 0.2 – 0.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3 times daily. *Children between 4 and 12 years of age* Herbal preparations C, D, F: C) Liquid extract *4-12 years of age* Single dose 0.33 g, 3 times daily D) Tincture *4-12 years of age* Single dose 0.3 – 0.5 ml, 3 times daily F) Soft extract *4-6 years of age* Single dose 0.12 g, 3 times daily *6-12 years of age* Single dose 0.12 g, 3-4 times daily ***Herbal preparations A, B, E, G, H, I***: The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). ***Herbal preparations C, D, F:*** The use in children under 4 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** If the symptoms persist longer than 1 week, a doctor or a qualified health care practitioner should be consulted.

Well-established use	Traditional use
	Method of administration Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Herbal preparations A, B, E, G, H, I: The use in children under 12 years of age has not been established due to lack of adequate data. ***Herbal preparations C, D, F:*** The use in children under 4 years of age is not recommended because medical advice should be sought. ***All herbal preparations:*** 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 tinctures and 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.

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

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

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
	None known. If adverse reactions 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

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