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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

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

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COMMUNITY HERBAL MONOGRAPH ON *PRIMULA VERIS* L. AND *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 Whole or cut, dried rhizome and root ii) Herbal preparations A) Dry extract (3-9:1), extraction solvent ethanol 40-50 % (v/v) B) Liquid extract (1:1), extraction solvent ethanol 70 % (v/v), C) Liquid extract (1:2.0-2.5), extraction solvent ethanol 70% (v/v) D) Tincture (1:5), extraction solvent ethanol 70 % (v/v) E) Soft extract (5-10:1), extraction solvent water F) Soft extract (1-4:1), extraction solvent ethanol 20-55% (v/v) G) Soft extract (6-10:1), extraction solvent methanol, water, ammonia solution 10% (50,0:49,5:0,5) H) Soft extract (6-10:1), extraction solvent methanol 50% I) Comminuted herbal substance for tea preparation

[1] The material complies with the Eur. Ph. monograph (ref. 01/2005:1364)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance or comminuted herbal substance for tea preparation or 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

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults, elderly* ***Single dose*** Herbal substance for tea preparation: 0.2 - 0.5 g Herbal preparations: A) Dry extract (according to ÖAB[3] with DER 3-3.5:1): 0.1 – 0.2 g B) Liquid extract: 0.5 g C) Liquid extract: 0.6 g D) Tincture: 0.5 – 1 g G) Soft extract: 22.5 mg I) Comminuted herbal substance for tea preparation: 0.2 – 0.5 g 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] Austrian pharmacopoeia (current edition)

Recommended mean daily doses
Herbal substance for tea preparation: 0.5 - 1.5 g

Herbal preparations:

A) Dry extract (according to ÖAB with DER 3-3.5:1): 0.3 – 0.6 g
B) Liquid extract: 1.5 g
C) Liquid extract: 2.4 g
D) Tincture: 1.5 – 3 g
G) Soft extract: 67.5 mg
I) Comminuted herbal substance for tea preparation: 0.5 - 1.5 g

Preparations A (different DER to ÖAB), E, F, H: daily dosage equivalent to 0.5 – 1.5 g herbal substance (depending on the actual DER)

Dosage frequency: May be taken every 2 to 3 hours (up to a maximum 3 times daily)

Children between 4 and 12 years of age

Herbal preparations:

C) Liquid extract
4-12 years of age

Single dose	***Dosage frequency***	***Daily dose***
0.33 g	3 times daily	1.0 g

D) Tincture
4-12 years of age

Single dose	***Dosage frequency***	***Daily dose***
0.3 – 0.5 ml	3 times daily	0.9 – 1.5 ml

F) Soft extract
4-6 years of age

Single dose	***Dosage frequency***	***Daily dose***
0.12 g	3 times daily	0.35 g

6-12 years of age

Single dose	***Dosage frequency***	***Daily dose***
0.12 g	3 to 4 times daily	0.35 g to 0.5 g

The use in children under 4 years of age is not recommended (see 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. **Method of administration** Oral use. Tea preparation: 0.2 to 0.5 g of herbal substance or comminuted herbal substance for decoction, infusion or macerate. As an expectorant one cup of tea every 2 to 3 hours.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other Primula species. Children with a history of acute obstructive laryngitis. Asthma.

4.4. Special warnings and precautions for use

Well-established use	Traditional use The use in children under 4 years of age is not recommended because medical advice should be sought. 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. Pregnancy and lactation

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

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
	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.

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

7 September 2007