The European Agency for the Evaluation of Medicinal Products
Evaluation of Medicines for Human Use

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WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

FINAL PROPOSAL FOR A CORE DATA FOR PRIMULA RADIX

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Final Proposal for a core-data for Primula radix (*Primula veris* L.)

The Working Party on Herbal Medicinal Products proposes the following core-data for Primula radix.

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Whole or cut, dried rhizome and root of *Primula veris* L. (synonym: *Primula officinalis* (L.) Hill) or *Primula elatior* (L.) Hill for oral administration.[1]

Herbal preparation to be specified for the individual finished product:
Extractum Primulae (3-9:1; 40-50 % v/v ethanol)
Extractum Primulae fluidum (1:2.0 – 2.5; 70 % m/m ethanol)
Tinctura Primulae (1:5; 70 % v/v ethanol)
Sirupus Primulae (Austrian Pharmacopoeia)

3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Herbal medicinal product for the relief of symptoms of the upper respiratory tract in coughs and colds with viscous mucilage[2].

4.2 Posology and method of administration

Dosage

Adults

Recommended single doses:
Herbal substance: 0.2 to 0.5 g
Herbal preparations:
Extractum Primulae: 0.1 – 0.2 g
Extractum Primulae fluidum: 0.5 g
Tinctura Primulae: 0.5 – 1 g
Sirupus Primulae(Austrian Pharmacopoeia): 5 – 10 ml

Recommended mean daily doses:
Herbal substance: 0.5 – 1.5 g
Tinctura Primulae: 1.5 – 3 g

[1] The herbal drug complies with the European Pharmacopoeia
[2] Decision by majority

Elderly
Doses as for adults

Adolescents (from 12 years)
The same doses as for adults may be applied.

Infants and children

Recommended single doses:
Herbal substance:
under 1 year: 0.02 – 0.1 g
1 – 4 years: 0.05 – 0.2 g
4 -11 years: 0.2 – 0.3 g

Recommended daily doses
Herbal substance:
under 1 year: 0.05 – 0.3 g
1 – 4 years: 0.2 – 0.6 g
4 -11 years: 0.5 – 1.0 g

Dosage frequency: May be taken every 2 to 3 hours

Dosage adjustment in specific patient groups: Not necessary

Method of administration

For oral administration

Tea preparation: 0.2 to 0.5 g of finely crushed drug or roughly powdered drug for decoction. As an expectorant one cup of tea every 2 to 3 hours.

Duration of use

No restriction (See section 4.4. Special warnings and precautions for use)

Intake of the product in relation to food intake: Not relevant

4.3 Contraindications

Hypersensitivity to the active substance (or any residues), to other Primula species (e.g. primrose), and/or to excipients.

4.4 Special warning and precautions for use

Caution is recommended in patients with gastritis or gastric ulcer.

The patient should be advised to consult a physician when dyspnoea, fever or purulent sputum occur, or when the symptoms persist or worsen.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Pregnancy and lactation

Because data on the use during pregnancy and lactation are not available, the use is not recommended as a general precaution.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

In very rare cases gastric disorders and nausea may occur.

4.9 Overdose

Overdose may lead to stomach upset, vomiting or diarrhoea.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Expectorants
ATC-Code: R05CA

Primula root has an expectorant action arising primarily from local irritation of the gastric mucosa by saponins, which are poorly absorbed; this provokes a reflex increase in bronchial secretion, which dilutes the mucus and reduces its viscosity.
The expectorant effects of Primula root preparations have long been recognised empirically; the uses are made plausible by pharmacological data.
Level of evidence: level IV[3]

5.2 Pharmacokinetic properties

No specific data are available on the pharmacokinetics of Primula root saponins. In general, saponins are poorly absorbed by the body.

5.3 Preclinical safety data

The toxic effects of Primula root are primarily due to the saponins, which may damage the cell membranes; this results in local irritation and in higher doses in cytotoxicity. After oral administration no signs of absorption of toxic doses have been found.

6 Date of compilation

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[3] Points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications (EMEA/HMPWP/23/99)

