EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Potentilla erecta* (L.) Raeusch., rhizoma

Final

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BG (bălgarski):	LT (lietuvių kalba):
CS (čeština): nátržníkový oddenek	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch): Tormentillwurzelstock, Blutwurz	NL (nederlands): Tormentil
EL (elliniká): ρίζα Πενταφύλλου του ορθίου	PL (polski):
EN (English): tormentil	PT (português):
ES (espanol):	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
FR (français):	SV (svenska):
HU (magyar):	*IS (íslenska)*:
IT (italiano):	*NO (norsk)*:

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Community herbal monograph on *Potentilla erecta* (L.) Raeusch., rhizoma

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 *Potentilla erecta* (L.) Raeusch., rhizoma (tormentil) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (V/V) [3] c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V) d) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V) e) Dry extract (DER 3.5-4.5:1), extraction solvent ethanol 60% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for infusion or decoction preparation for oromucosal use. Herbal preparations b), c), d) and e) in liquid dosage forms for oral use.

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:1478).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
3 The tincture complies with the Ph. Eur. monograph (ref.: 01/2008:1895).

	Herbal preparation b) in liquid dosage forms for oromucosal 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
	Indication 1) Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea. Indication 2) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the oral mucosa. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* Indication 1) (oral use) a) Comminuted herbal substance: As infusion: single dose 1.4-4 g, several times daily up to a maximum daily dose of 12 g. As decoction: single dose 1.4-3 g, several times daily up to a maximum daily dose of 6 g. b) Tincture (1:5, ethanol 70%): Single dose: 1-2 ml in water, 3 times daily. c) Tincture (1:5, ethanol 45%): Single dose: 2-4 ml, 3 times daily. d) Liquid extract: Single dose: 2-4 ml, 3 times daily.

	e) Dry extract: Single dose: 400 mg, 3 times daily. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) (oromucosal use) a) Comminuted herbal substance: As infusion: 1.3–2 g per 100 ml of water. As decoction: 0.8–3 g per 100 ml of water. Rinse the mouth several times daily. b) Tincture (1:5, ethanol 70%): Single dose: 1-5 ml per 150 ml of water. Rinse the mouth several times daily. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) If the symptoms persist longer than 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) 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. **Method of administration** Indication 1) Oral use. Indication 2) Oromucosal 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
	Indication 1) If recurrent diarrhoea or bloody stools occur, a doctor or a qualified health care practitioner should be consulted. Indications 1) and 2) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures 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
	Indication 1) Internal absorption of concomitantly administered medicine may be delayed. For this reason the product should be taken 1 hour or more before or after intake of other medicinal products. Indication 2) None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. 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
	Indication 1) Mild gastrointestinal complaints such as nausea and vomiting 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. Indication 2) 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
	No case of overdose has been reported.

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. Adequate 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

25 November 2010