



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Capsella bursa-pastoris* (L.) Medikus, herba

Draft

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BG (bългарски): CS (čeština): DA (dansk): DE (Deutsch): Hirtentäschelkraut EL (elliniká): EN (English): shepherd's purse ES (español): bolsa de pastor ET (eesti keel): FI (suomi): FR (français): bourse à pasteur HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): herderstasje PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): IS (íslenska): NO (norsk):
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Community herbal monograph on *Capsella bursa-pastoris* (L.) Medikus, herba.

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>Capsella bursa-pastoris</i> (L.) Med. (syn.: <i>Thlaspi bursa-pastoris</i> L.), herba (shepherd's purse)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>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>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for the reduction of heavy menstrual bleeding in women with regular menstrual cycles, after serious</p>

¹ The material complies with (ref.: Ph. Fr. (10^e edition) as amended by additive no 38, 1997).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	<p>conditions have been excluded by a medical doctor.</p> <p>The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Use to be started 3-5 days before the menstruation and to be applied during the whole menstrual cycle.</p> <p>a) Comminuted herbal substance: 1-5 g as a single dose for the preparation of herbal tea, 2-4 times daily (daily dosage: 3-20 g).</p> <p>b) Liquid extract: 1-4 ml as a single dose, 3 times daily.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>If the symptoms persist 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>

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
	<p>The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice.</p> <p>If the symptoms worsen during the use of the</p>

Well-established use	Traditional use
	<p>medicinal product, 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. 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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

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. 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