



6 May 2014
EMA/HMPC/198793/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Arnica montana* L., flos

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2012 May 2012 November 2012 March 2013 May 2013
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	9 July 2013
End of consultation	15 December 2013
Rediscussion in Working Party on Community monographs and Community list (MLWP)	March 2014
Adoption by Committee on Herbal Medicinal Products (HMPC)	6 May 2014

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Arnica montana</i> L., flos; Arnica flower
-----------------	--

BG (bългарски): Арника, цвят CS (čeština): květ prhy chlumní DA (dansk): Arnikablomst DE (Deutsch): Arnikablüten EL (ελληνικά): άνθος αρνακίδος (αρνίκης)- άνθος αρνίκης EN (English): Arnica Flower ES (español): Árnica, flor de ET (eesti keel): arnikaõisik FI (suomi): etelänarnikki, kukka FR (français): Arnica (fleur d') HU (magyar): Hegyi árnikavirág HR (hrvatska): brđankin cvijet IT (italiano): Arnica fiore	LT (lietuvių kalba): Arnikų žiedai LV (latviešu valoda): Arnikas ziedi MT (malti): Fjura ta' l-Arnika NL (nederlands): Valkruid, Wolverlei PL (polski): Kwiat arniki PT (português): Arnica, flor RO (română): floare de arnică SK (slovenčina): Kvet arniky horskej SL (slovenščina): cvet navadne arnike SV (svenska): Arnikablomma <i>IS (islenska):</i> <i>NO (norsk): Arnikablomst</i>
---	--



Community herbal monograph on *Arnica montana* L., flos

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>Arnica montana</i> L., flos</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Tincture (DER 1:10), extraction solvent: ethanol 70% (v/v)</p> <p>b) Tincture (DER 1:10), extraction solvent: ethanol 60% (v/v)</p> <p>c) Tincture (DER 1:5), extraction solvent: ethanol 60% (v/v)</p> <p>d) Liquid extract of fresh flowers (DER 1:20), extraction solvent: ethanol 50% (m/m)</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in semi-solid and liquid dosage forms for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² When dried, the material complies with the Ph. Eur. monograph (ref.: 04/2008, 1391)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for the relief of bruises, sprains and localised muscular pain.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p><i>Adolescents, adults and elderly</i></p> <p>a) semi-solid dosage form (20-25% tincture in base):</p> <p>Apply a thin layer on the affected area, two to three times daily.</p> <p>b) liquid dosage form (2.5 ml as an impregnated dressing):</p> <p>Apply on the affected area, three to four times daily.</p> <p>c) semi-solid dosage form (20% tincture in base)</p> <p>Apply a thin layer on the affected area, two to three times daily.</p> <p>d) semi-solid dosage form (50% liquid extract in base):</p> <p>Apply a thin layer on the affected area, two to four times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions of use').</p> <p>Duration of use</p> <p>If the symptoms persist after 3 to 4 days 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>Cutaneous use.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>The preparation should not be used on broken skin.</p>

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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy is not recommended.</p> <p>No fertility data available.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	Not relevant.

4.8. Undesirable effects

Well-established use	Traditional use
	Allergic reactions such as itching, redness of the skin and eczema may occur. The frequency is not

Well-established use	Traditional use
	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

6 May 2014