EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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BG (bălgarski): Арника, цвят CS (čeština): květ prhy chlumní DA (dansk): Arnikablomst DE (Deutsch): Arnikablüten EL (elliniká): ἀνθος αρνακίδος 9αρνικης)- ἀνθος αρνίκης EN (English): Arnica Flower ES (espanol): Árnica, flor de ET (eesti keel): arnikaõisik FI (suomi): etelänarnikki, kukka FR (français): Arnica (fleur d') HU (magyar): Hegyi árnika virág HR (hrvatska): 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 *IS (íslenska)*: *NO (norsk): Arnikablomst*

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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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended Arnica montana L.,flos i) Herbal substance Not applicable. ii) Herbal preparations a) Tincture (1:10), extraction solvent: ethanol 70% (V/V) b) Tincture (1:5), extraction solvent: ethanol 60% (V/V) c) Liquid extract of fresh flowers (1:20), extraction solvent: ethanol 50% (m/m)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in semi-solid dosage forms for cutaneous 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 for the relief of bruises, sprains and localised muscular pain.

[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)

Well-established use	**Traditional use**
	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**
	Adolescents, adults and elderly a) semi-solid dosage form (21.5% tincture in ointment base) Apply a thin layer on the affected area, two to three times daily. b) semi-solid dosage form (20% tincture in base) Apply a thin layer on the affected area, two to three times daily. c) semi-solid dosage form (50% liquid extract in base) Apply a thin layer on the affected area, two to four times daily. The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions of use'). **Duration of use** 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. **Method of administration** Cutaneous use.

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**
	The use in children under 12 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. The semi-solid dosage form should not be used on broken skin.

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

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 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

9 July 2013