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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Arnica montana* L., flos

Draft – Revision 1

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BG (bulgarski): Арника, цвят CS (čeština): květ prhy chlumní DA (dansk): Arnikablomst DE (Deutsch): Arnikablüten EL (elliniká): 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') HR (hrvatski): Hegyi árnika virág HU (magyar): 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 IS (íslenska): NO (norsk): Arnikablomst
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European Union 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 <i>Arnica montana</i> L., flos (arnica flower) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Tincture (ratio herbal substance to extraction solvent 1:10); extraction solvent: ethanol 70% (V/V) c) Tincture (ratio herbal substance to extraction solvent 1:10); extraction solvent: ethanol 60% (V/V) d) Fluid extract (DER 1:1); extraction solvent: ethanol 60% (V/V) e) Liquid extract of fresh flowers (DER 1:20); extraction solvent: ethanol 50% (m/m) f) Liquid extract (1:3.5-4.5); extraction solvent: refined sunflower oil

3. Pharmaceutical form

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

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>Indication 1) Traditional herbal medicinal product for the relief of bruises, sprains and localised muscular pain.</p> <p>Indication 2) Traditional herbal medicinal product for inflammations as a result of insect bites.</p> <p>Indication 3) Traditional herbal medicinal product for treatment of small boils (furuncles).</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1</p> <p><u>Preparation a)</u> <i>Children above 3 years of age, adolescents, adults and elderly</i></p> <p>2 g of the comminuted herbal substance in 100 ml of boiling water, let steep for 10-15 min; warm infusion to be applied as impregnated dressing. Apply 3-4 times daily on the affected area.</p> <p>The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions of use').</p> <p><u>Preparation b)</u> <i>Children above 3 years of age, adolescents, adults and elderly</i></p> <ul style="list-style-type: none">Semi-solid dosage forms (5-25% tincture in base). Apply a thin layer on the affected area, 2 to 4 times daily.Liquid dosage form (only diluted tincture:

Well-established use	Traditional use
	<p>1:3-10 with water). Apply a few milliliters of dilution to the affected area directly or as impregnated dressing, 2 to 4 times daily</p> <p>The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions of use').</p> <p><u>Preparation c)</u> <i>Adolescents, adults and elderly</i> 2.5 ml for preparation of an impregnated dressing. Apply on the affected area, three 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><u>Preparation d)</u> <i>Children above 3 years of age, adolescents, adults and elderly</i> Semi-solid dosage forms (4% fluid extract in base). Apply a thin layer on the affected area, two to three times daily.</p> <p>The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions of use').</p> <p><u>Preparation e)</u> <i>Adolescents, adults and elderly</i> In semi-solid dosage forms (50% liquid extract in base). 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><u>Preparation f)</u> <i>Adolescents, adults and elderly</i> In semi-solid dosage forms (10% liquid extract in base). Apply a thin layer on the affected area, two to three times daily.</p>

Well-established use	Traditional use
	<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>Indication 2</p> <p><u>Preparation a)</u> <i>Children above 3 years of age, adolescents, adults and elderly</i></p> <p>2 g of the comminuted herbal substance in 100 ml of boiling water, let steep for 10-15 min; warm infusion to be applied as impregnated dressing. Apply 3-4 times daily on the affected area.</p> <p><u>Preparation b)</u> <i>Children above 3 years of age, adolescents, adults and elderly</i></p> <ul style="list-style-type: none"> • Semi-solid dosage form (5% tincture in base). Apply a thin layer on the affected area, 2 to 4 times daily. • Liquid dosage form (only diluted tincture: 1:3-10 with water). Apply a few milliliters of dilution to the affected area directly or as impregnated dressing, 2 to 4 times daily. <p>The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions of use').</p> <p><u>Preparation f)</u> <i>Adolescents, adults and elderly</i></p> <p>In semi-solid dosage forms (10% liquid extract in base). Apply a thin layer on the affected area, two to three 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>Indication 3</p> <p><u>Preparation a)</u> <i>Adolescents, adults and elderly</i></p> <p>2 g of the comminuted herbal substance in 100 ml of boiling water, let steep for 10-15 min;</p>

Well-established use	Traditional use
	<p>warm infusion to be applied as impregnated dressing. Apply 3-4 times daily on the affected area.</p> <p><u>Preparation b)</u> <i>Adolescents, adults and elderly</i> Liquid dosage form (only diluted tincture: 1:3-10 with water). Apply a few milliliters of dilution to the affected area directly or as impregnated dressing, 2 to 4 times daily.</p> <p><u>Preparation f)</u> <i>Adolescents, adults and elderly</i> In semi-solid dosage forms (10% liquid extract in base). Apply a thin layer on the affected area, two to three 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><u>Preparation a, b, d:</u> The use in children under 3 years of age is not recommended because of concerns requiring medical advice.</p>

Well-established use	Traditional use
	<p><u>Preparation c, e, f:</u></p> <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> <p>The preparations should not be applied near the eyes or mucous membranes.</p> <p>The tincture should be diluted before use.</p> <p>For tinctures and 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> <p><u>Indications 2 and 3)</u></p> <p>If fever or signs of exacerbating skin infection are observed, a doctor or a qualified health care practitioner should be consulted.</p> <p><u>Indication 3</u></p> <p>Small boils (furuncles) in the face should be treated by a medical doctor.</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 and lactation 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
	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>Immune system disorders: Allergic reactions such hypersensitivity may occur.</p> <p>Skin and subcutaneous tissue disorders: Allergic reactions such as itching, redness of the skin and eczema may occur. The frequency is not known.</p> <p>If other adverse reactions not mentioned above 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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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

19 March 2025