

## ARNICA

For arnica products in semi-solid dosage forms, refer to the “Arnica semi-solid dosage forms” monograph.

The arnica monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

### Notes:

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
- ▶ The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

**Date:** June 24, 2011

**Proper name(s):** *Arnica montana* L. (Asteraceae) (USDA 2009; McGuffin et al. 2000)

**Common name(s):**

- ▶ Arnica (USDA 2009; McGuffin et al. 2000)
- ▶ European arnica (USDA 2009; McGuffin et al. 2000)

**Source material(s):** Flower (Bradley 2006; Mills and Bone 2005; Wichtl 2004)

**Route(s) of administration:** Topical

**Dosage form(s):** The dosage forms suited to topical administration except semi-solid dosage forms, such as creams, gels, ointments, and salves.

**Use(s) or Purpose(s):** Statement(s) to the effect of:  
  
(Traditionally) used in Herbal Medicine to help relieve pain and/or inflammation in muscles and joints (e.g. sprains, bruises, joint pain) (Bradley 2006; ESCOP 2003; Williamson 2003; Felter 2001 [1922]; Blumenthal et al. 2000; Felter and Lloyd 1983 [1898]; Grieve 1971 [1931]).

**Note:**

Claims for traditional use must include the term “Herbal Medicine”.

**Dose(s):**

**Subpopulation(s):** For adults ( $\geq 19$  years) and adolescents (13-18 years)

**Quantity(ies):**

- Infusion: 2 g of arnica flowers (Bradley 2006; Wichtl 2004)  
**Directions for use:** Pour 100 ml boiling water over flowers and infuse from 10-15 minutes (Bradley 2006; Wichtl 2004). Let cool.
- Tincture: 200 g powdered dried flowers (1:5, diluted alcohol) (Remington and Woods 2008 [1918]; Bradley 2006; Mills and Bone 2005; Fenner 2001 [1918])  
**Directions for use:** For each millilitre of tincture, dilute with 3-10 ml of water (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Blumenthal et al. 2000).
- Tincture: 100 g powdered dried flowers (1:10, 45% alcohol) (Remington and Woods 2008 [1918]; Bradley 2006; Mills and Bone 2005)  
**Directions for use:** For each millilitre of tincture, dilute with 3-10 ml of water (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Blumenthal et al. 2000).
- Medicated oil: 1:5 ratio of arnica flower to vegetable fatty oil (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000; Cech 2000)

**Directions for use:** Statement(s) to the effect of:

For all products:

- ▶ Apply thinly and evenly to affected area up to 3 to 4 times per day (Pray 2006). Rub and/or massage into skin until the preparation disappears.
- ▶ For external use only.
- ▶ Avoid contact with the eyes and mucous membranes.
- ▶ Do not apply to wounds or damaged skin (Brinker 2010; Bradley 2006; Pray 2006; Mills and Bone 2005; Felter 2001 [1922]).
- ▶ Do not bandage (Pray 2006; Felter 2001 [1922]).
- ▶ Do not apply with external heat, such as an electric heating pad, as this may result in excessive skin irritation or skin burn (Pray 2006).

For breastfeeding women:

Do not apply on or near the nipple (Brinker 2010; Mills and Bone 2005).

Refer to Appendix 1 for examples of dosage preparations and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration of use:** No statement required.

**Risk information:** Statement(s) to the effect of:

**Caution(s) and warning(s):** Consult a health care practitioner if symptoms persist or worsen.

**Contraindication(s):** Do not use if you are allergic to plants of the Asteraceae/Compositae/Daisy family (Brinker 2010; Bradley 2006; Pray 2006; Mills and Bone 2005).

**Known adverse reaction(s):** Hypersensitivity/allergy has been known to occur; in which case, discontinue use (Brinker 2010; Bradley 2006; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003).

**Non-medicinal ingredients:** Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

**Specifications:**

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1 Monographs published in the British and the European pharmacopoeias

Pharmacopoeia	Monograph
British Pharmacopoeia (BP)	Arnica Flower
European Pharmacopoeia (Ph.Eur.)	Arnica Flower (Arnicae flos) Arnica Tincture (Arnicae tinctura)

## References cited:

Blumenthal M, Goldberg A, Brinckmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000.

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Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association; 2006.

Brinker F. Final Updates and Additions for Herb Contraindications and Drug Interactions, 3<sup>rd</sup> edition. Sandy (OR): Eclectic Medical Publications. [Internet]. [Last update 2010 July 13; Accessed 2011 June 23]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

Cech R. Making Plant Medicine. Williams (OR): Horizon Herbs; 2000.

ESCOP 2003: E/S/C/O/P Monographs: The Scientific Foundation for Herbal Medicinal Products. 2<sup>nd</sup> edition. Exeter (GB): ESCOP, the European Scientific Cooperative on Phytotherapy in collaboration with Georg Thieme Verlag and Thieme; 2003.

Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Cincinnati (OH): John K. Scudder; 1922. [Internet]. Reprinted and abridged by Southwest School of Botanical Medicine; 2001. [Accessed 2011 February 2]. Available from: [http://www.swsbm.com/FelterMM/Felters\\_Materia\\_Medica.pdf](http://www.swsbm.com/FelterMM/Felters_Materia_Medica.pdf)

Felter HW, Lloyd JU. King's American Dispensatory. Volume 1, 18<sup>th</sup> edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Fenner B. A Complete Formulary and Hand-book of Valuable Information for Pharmacists, Manufacturers of Chemical and Pharmaceutical Preparations, Physicians and Students of Pharmacy and Medicine. 6th edition. Westfield (NJ): B. Fenner, Publisher and Proprietor; 1888. [Internet]. Scanned by Southwest School of Botanical Medicine; 2001. [Accessed 2011 January 28]. Available from: <http://www.swsbm.com/Fenners/Complete%20Formulary-3b.pdf>

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Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005.

Ph.Eur. 2011: European Pharmacopoeia, 7<sup>th</sup> edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), 2011.

Pray WS. Non-Prescription Product Therapeutics. 2nd edition. New York (NY): Lippincott Williams & Wilkins; 2006.

Remington JP, Woods HC, editors. The Dispensatory of the United States of America, 20th edition, 1918. [Internet]. Scanned by Southwest School of Botanical Medicine as Abridged - botanicals only; 2008. [Accessed 2011 January 28]. Available from: <http://www.swsbm.com/Dispensatory/USD-1918-complete.pdf>

USDA 2009: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Online Database]. National Germplasm Resources Laboratory, Beltsville (MD). [*Arnica montana* L. Last updated 2009 December 28; Accessed 2011 June 23]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl)

Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. 3<sup>rd</sup> edition. Stuttgart (DE): Medpharm Scientific Publishers; 2004.

Williamson EM, Evans FJ, Wren RC. Potter's Herbal Cyclopaedia: The Authoritative Reference Work on Plants with a Known Medicinal Use. Saffron Walden (GB): The C.W. Daniel Company Limited; 2003.

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Blumenthal M. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Austin (TX): American Botanical Council in cooperation with Integrative Medicine Communications; 1998.

Bove M. An Encyclopedia of Natural Healing for Children and Infants. 2<sup>nd</sup> edition. New York (NY): McGraw-Hill Publishing, Incorporated; 2001.

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Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine. Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006.

Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists: With reference to Commission E Monographs of the Federal Department of Health in Germany. Includes 100 Commission E monographs and 15 ESCOP Monographs. Stuttgart (DE): Medpharm Scientific Publishers; 1997.

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## Appendix 1: Examples of dosage preparations and directions for use

### Tincture:

- ▶ 1:10 extraction ratio (Bradley 2006)  
**Directions for use:** For each millilitre of tincture, dilute with 3-10 ml of water (Bradley 2006). Apply to affected area as needed.
- ▶ 1:5 extraction ratio (Mills and Bone 2005)  
**Directions for use:** For each millilitre of tincture, dilute with 5 ml of water (Mills and Bone 2005). Apply to affected area as needed.
- ▶ Tincturae Arnicae: 1 part drug to 10 parts ethanol 70% v/v, manufactured according to DAB Tincturae monograph (Wichtl 2004)
- ▶ Tincture of Arnica Flowers: No. 20 powder, 100 grammes; Alcohol (45 per cent.), sufficient to produce 1000 millilitres. Moisten the powder with two hundred millilitres of the Alcohol, and complete the percolation process. (Remington and Woods 2008 [1918])
- ▶ Tincture of Arnica Flowers: No. 20 powder, two hundred grammes [or 7 ounces av., 24 grains]; Diluted Alcohol, a sufficient quantity, to make one thousand mils [or 33 fluidounces, 61/2 fluidrachms]. (Remington and Woods 2008 [1918])
- ▶ Tinctura Arnicae Florum / Tincture of Arnica Flowers  
Arnica Flowers, 20 parts or 6 ¼ ounces av.  
Diluted Alcohol, sufficient to make 100 parts or 2 pints.  
Moisten the Arnica Flowers with 12 fl. ounces of diluted Alcohol and macerate for 24 hours, then pack it firmly in a cylindrical percolator and gradually pour diluted Alcohol upon it until 2 pints of Tincture are obtained. (Fenner 2001 [1888])
- ▶ The German formula directs 1 part of the Flowers to 10 parts of diluted Alcohol (Fenner 2001 [1888]).
- ▶ Arnica tincture / Arnicae tinctura  
DEFINITION  
Tincture produced from Arnica flower  
Content: minimum of 0.04 per cent sesquiterpene lactones expressed as dihydrohelenalin tiglactate (C<sub>20</sub>H<sub>26</sub>O<sub>5</sub>; M<sub>r</sub> 346.42).  
PRODUCTION  
The tincture is produced from the herbal drug by a suitable procedure using 10 parts of ethanol (60-70 % V/V) for 1 part of drug. (Ph.Eur. 2010)

### Infusion

2 g drug/herb per 100 ml water (Wichtl 2004; Blumenthal et al. 2000)