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 (≥ 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

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
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<tr>
<td>British Pharmacopoeia (BP)</td>
<td>Arnica Flower</td>
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<tr>
<td>European Pharmacopoeia (Ph.Eur.)</td>
<td>Arnica Flower (Arnicae flos)</td>
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<tr>
<td></td>
<td>Arnica Tincture (Arnicae tinctura)</td>
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</tbody>
</table>
References cited:


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


References reviewed:


reference to Commission E Monographs of the Federal Department of Health in Germany.
Includes 100 Commission E monographs and 15 ESCOP Monographs. Stuttgart (DE):

February 1]. Available from: http://www.medicinescomplete.com
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 tiglate (C_{20}H_{26}O_{5}; M_r 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)