

## NATURAL HEALTH PRODUCT

### ARNICA – *ARNICA MONTANA*

This 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 and/or statements are synonymous. Either term or statement may be selected by the applicant.
- ▶ For arnica products in semisolid dosage forms, refer to the “Arnica - Semisolid dosage forms” monograph.

**Date** August 5, 2019

#### Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Arnica montana</i>	<ul style="list-style-type: none"> <li>▶ Arnica</li> <li>▶ Arnica flower</li> <li>▶ European arnica</li> <li>▶ Leopard's bane</li> <li>▶ Leopardsbane</li> <li>▶ Mountain arnica</li> <li>▶ Mountain-tobacco</li> <li>▶ Wolf's bane</li> </ul>	<i>Arnica montana</i>	Flower	Dried
<i>Arnica montana</i>	Arnica tincture <sup>1</sup>	<i>Arnica montana</i>	Flower	Dried
<i>Arnica montana</i>	Oil of Arnica <sup>2</sup>	<i>Arnica montana</i>	Flower	Dried

References: Proper name: USDA 2019, McGuffin et al. 2000; Common names: USDA 2019, McGuffin et al. 2000; Source information: Bradley 2006, Mills and Bone 2005, Wichtl 2004.

<sup>1</sup>Arnica tincture must be prepared with diluted alcohol with an extract ratio of 1:5 or 1:10 (Bradley 2006; Mills and Bone 2005; Fenner 1918; Remington and Woods 1918).

<sup>2</sup>Oil of Arnica must be prepared with a 1:5 ratio of arnica flower in vegetable fixed oil (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000; Cech 2000).

#### Route of administration

Topical



## Dosage form(s)

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

This monograph excludes the following topical semi-solid dosage forms: creams, gels, lotions, ointments, pastes and salves. It also excludes plasters and patches.

## Use(s) or Purpose(s)

(Traditionally) used in Herbal Medicine to help relieve pain and/or inflammation in muscles and joints (such as sprains, bruises and/or joint pain) (Bradley 2006; ESCOP 2003; Williamson 2003; Blumenthal et al. 2000; Felter and Lloyd 1983; Grieve 1971; Felter 1922).

### Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

## Dose(s)

### Subpopulation(s)

Adolescents 12-17 years and Adults 18 years and older

### Quantity(ies)

#### *Arnica*

Method of preparation: Infusion

50 - 100 millilitres of extract and a Quantity crude equivalent of 1 - 2 grams of dried flowers with an extract ratio of 1:50 (Bradley 2006; Wichtl 2004).

Methods of preparation: Dry, Powdered

1 - 2 grams of dried flowers (Bradley 2006; Wichtl 2004).

Note: Dried or powdered flowers should be prepared as an infusion (see direction for use).

#### *Oil of Arnica*

Method of preparation: Oil, Medicated from dried plant

1 - 15% of oil of Arnica (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000; Cech 2000).



## ***Arnica Tincture***

Method of preparation: Tincture

### *Undiluted*

100% of Arnica tincture

### *Diluted in water*

5 - 25% of Arnica tincture (Bradley 2006; Wichtl 2004; Williamson 2003; Blumenthal et al. 2000).

## **Direction(s) for use**

### *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 1922).
- ▶ Do not bandage (Pray 2006; Felter 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).
- ▶ Do not apply on or near the nipple if you are breastfeeding (Brinker 2010; Mills and Bone 2005).

### *Dried flower*

For each gram of dried flowers, pour 50 millilitres of boiling water and infuse from 10-15 minutes. Let cool (Bradley 2006; Wichtl 2004).

### *Powdered flower*

For each gram of dried powdered flowers, pour 50 millilitres of boiling water and infuse from 10-15 minutes. Let cool (Bradley 2006; Wichtl 2004).

### *Undiluted Arnica Tincture (100%)*

For each millilitre of tincture, dilute with 3-10 millilitres of water (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Blumenthal et al. 2000).



### **Duration(s) of use**

No statement required.

### **Risk information**

#### **Caution(s) and warning(s)**

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

#### **Contraindication(s)**

No statement required.

#### **Known adverse reaction(s)**

Stop use if hypersensitivity/allergy occurs (Brinker 2010; Bradley 2006; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003).

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### **Storage conditions**

No statement required.

### **Specifications**

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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