Health Canada Santé Canada

NATURAL HEALTH PRODUCT

ARNICA – *ARNICA MONTANA*
Semisolid dosage forms

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 using dosage forms other than the semisolids forms listed below, refer to the "Arnica" monograph.

Date August 5, 2019

Proper name(s), Common name(s), Source material(s)

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

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
Arnica montana	Arnica tincture[1]	*Arnica montana*	Flower	Dried
Arnica montana	Oil of Arnica[2]	*Arnica montana*	Flower	Dried

References: Proper name: USDA 2019, McGuffin et al. 2000; Common names: USDA 2019, McGuffin et al. 2000; Source material: Bradley 2006; Wichtl 2004; Cech 2000.

[1]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).

[2]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)

The only acceptable dosage forms are the following topical semisolid dosage forms: creams, gels, lotions, ointments, pastes and salves.

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; Wichtl 2004; Williamson 2003; Blumenthal et al. 2000).

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

Dose(s)

Subpopulation(s)

Children 2-11 years, Adolescents 12-17 years and Adults 18 years and older

Quantity(ies)

Arnica Tincture

Method of preparation: Tincture

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

Oil of Arnica

Method of preparation: Oil, Medicated from dried plant

Semisolid dosage forms containing 1 - 15% of oil of Arnica (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000; Cech 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; Cech 2000).
- Do not bandage (Pray 2006).
- 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).

Products for Children 2-11 years

Application should be supervised by an adult (Bove 2001).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Consult a health care practitioner 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; Cech 2000).

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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