ARNICA - SEMISOLID DOSAGE FORMS

For arnica products using dosage forms other than semisolids, refer to the "Arnica" monograph.

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 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; Wichtl 2004; Cech 2000)

Route(s) of administration: Topical

Dosage form(s): The only acceptable dosage forms are semisolids (e.g. 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; Wichtl 2004; Williamson 2003; Blumenthal et al. 2000).

Note: Claims for traditional use must include the term "Herbal Medicine".

Dose(s):

Subpopulation(s): For adults (≥ 19 years), adolescents (13-18 years), and children (2-12 years)

Quantity(ies):

- Semisolid dosage forms containing 5-25% arnica tincture (Bradley 2006; Wichtl 2004; Williamson 2003; Blumenthal et al. 2000).
  An acceptable arnica tincture preparation is defined in the Arnica monograph.

- Semisolid dosage forms containing 1-15% oil of arnica (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000; Cech 2000).
  An acceptable oil of arnica preparation is defined in the Arnica monograph.

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; 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).

For children (2-12 years):

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

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).

Known adverse reaction(s): Hypersensitivity/allergy has been known to occur; in which case, discontinue use (Brinker 2010; Bradley 2006; Cech 2000).

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*.

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Appendix 1: Examples of dosage preparations and directions for use

Ointment:

- Preparations containing 1-15% arnica oil (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000)
- Preparations containing 10-25% tincture (Bradley 2006)
- Preparations containing 20-25% tincture (Wichtl 2004; Blumenthal et al. 2000)

Directions for use: Apply to affected area as needed.