Arnica

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ARNICA - ARNICA MONTANA Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 60 KB) 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 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 on the label. Date February 28, 2025 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 Arnica montana Arnica Arnica flower European arnica Leopard's bane Leopardsbane Mountain arnica Mountain-tobacco Wolf's bane Arnica montana Flower Dry Arnica montana Arnica tincture 1 Arnica montana Flower Dry Arnica montana Oil of Arnica 1 Arnica montana Flower Dry References: Proper name: USDA 2024; Gardner and McGuffin 2013; Common names: USDA 2024; Gardner and McGuffin 2013; Source information: Bradley 2006; Mills and Bone 2005; Wichtl 2004. 1 Arnica tincture and Oil of Arnica must be prepared according to methods described in the 'Dose(s)' section below. Route of Administration Topical Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Cream; Gel; Liniment; Liquid; Loose; Lotion; Oil; Ointment; Paste; Powder; Salve; Solution; Spray; Topical liquid. 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; ESCOP 2003; Williamson 2003; Blumenthal et al. 2000; Felter and Lloyd 1983; Grieve 1971; Felter 1922). Notes For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Arnica is traditionally used in Herbal Medicine to help relieve pain and/or inflammation in muscles and joints). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Children 2-11 years, Adolescents 12-17 years, Adults 18 years and older. Quantity(ies) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% of dried flowers (Bradley 2006; Wichtl 2004). Note: Products in loose or powder dosage forms must be prepared as an infusion by the consumer and applied as a compress (see direction for use). Cream/Gel/Liniment/Liquid/Lotion/Oil/Ointment/Paste/Salve/Solution/Spray/Topical liquid dosage forms Methods of preparation: Decoction, Decoction concentrate, Infusion, Infusion concentrate 10 - 100% dried flower extract preparation in the finished product (Bradley 2006; Wichtl 2004; ESCOP 2003; Barnes et al. 2002; Mills and Bone 2000). Note: The extract ratio must be between 1:10 and 1:50. The formulation must be prepared in a way which is equivalent to a quantity of 10 to 20 milligrams crude dried flowers for 1 milliliter of finished product. For example, for a decoction prepared with a 1:20 w/v ratio, the concentration of decoction in the finished product must be 40% (10 - 20 mg crude dried flowers * 20 w/v (dilution) = 0.2 - 0.4 mL liquid extract in 1 mL finished product = 20 - 40% v/v extract preparation in the finished product). Method of preparation: Oil, Medicated from dried plant 1 - 15% of dried flower extract preparation in the finished product (Bradley 2006; Wichtl 2004; Blumenthal et al. 2000; Cech 2000). Note: Oil of Arnica must be prepared with a 1:5 ratio of arnica flower in vegetable fixed oil (e.g., olive oil, sunflower oil, etc.). Method of preparation: Tincture 5 - 33% of dried flower extract preparation in the finished product (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Williamson 2003; Blumenthal et al. 2000; Fenner 1918; Remington and Woods 1918). Notes: Arnica tincture must be prepared with an extract ratio between 1:5 and 1:10 and the solvent must be a mix of ethanol and water. For

liquid dosage forms, Arnica tincture must be further diluted in water to obtain a final concentration of 5 to 33% extract preparation (i.e., Arnica tincture) in the finished product. For example, for a tincture with a 1:5 w/v ratio, the concentration of tincture in the finished product must be 5 to 33%, resulting in a formulation prepared with an equivalent quantity of 10 to 67 milligrams crude dried flowers for 1 milliliter of finished product (10 - 67 mg crude dried flowers * 5 w/v (dilution) = 0.05 - 0.33 mL tincture in 1 mL finished product = 5 - 33% v/v extract preparation in the finished product). For semi-solid dosage forms, Arnica tincture must be diluted to reach a final concentration of 5 to 25% extract preparation (i.e., Arnica tincture) in the finished product. Combination rule No permitted combinations between the medicinal ingredients listed in Table 1 (i.e., arnica oil with arnica tincture and/or arnica infusion). Direction(s) for use All products Rub and/or massage into skin until the preparation disappears. Do not apply to wounds or damaged skin (Brinker 2010; Bradley 2006; Pray 2006; Mills and Bone 2005; Felter 1922). Do not tightly 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). Supervise children when they use this product (Bove 2001). Loose/Powder dosage forms Place [insert volume to be measured by consumer in order to obtain 1 to 2 grams dried flower, e.g., 1 teaspoon] of product in 1/2 cup (125 mL) of boiling water and infuse from 10-15 minutes. Let cool. Soak a small towel/pad/gauze/cotton in the product. Apply to affected area(s), up to 4 times per day (Bradley 2006; Pray 2006; Wichtl 2004; ESCOP 2003; Mills and Bone 2000). Liquid dosage forms (Liquid; Solution; Topical liquid) Soak a small towel/pad/gauze/cotton in the product. Apply to affected area(s), up to 4 times per day (Bradley 2006; Pray 2006; ESCOP 2003; Mills and Bone 2000). Spray dosage form Avoid inhaling or exposing others to spray. Cream/Gel/Liniment/Lotion/Oil/Ointment/Paste/Salve/Spray dosage forms Apply thinly and evenly to affected area(s), up to 4 times per day (Pray 2006). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) For external use only. When using this product avoid contact with the eyes and mucous membranes. If contact occurs, rinse thoroughly with water. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist, worsen, or re-occur within a few days. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy, rashes or burning discomfort occur (NIH 2023; 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Barnes J, Anderson LA, Phillipson JD. 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Louis (MO): Elsevier Churchill Livingstone; 2005. NIH 2023: National Institutes of Health. National Library of Medicine. LiverTox: Clinical and research information on drug-induced liver injury. Bethesday (MD): National Institute of Diabetes and Digestive and Kidney Diseases; 2023. [Accessed 2024 September 5]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK589897/ 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. Scanned by Southwest School of Botanical Medicine as Abridged - botanicals only; 2008. [Accessed 2024 May 16]. Available from: http://www.swsbm.com/Dispensatory/USD-1918-complete.pdf USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 May 13]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. 3rd 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. References Reviewed APhA 2002: Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. 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. 2nd edition. New York (NY): McGraw-Hill Publishing, Incorporated; 2001. BP 2011: British Pharmacopoeia 2011. Volume II. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA); 2010. Peirce A. Practical Guide to Natural Medicines. New York (NY): American Pharmaceutical Association; 1999. Ph.Eur. 2011: European Pharmacopoeia, 7th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM), 2011. Pizzorno JE, Murray MT, editors. Textbook of Natural Medicine. Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2023 August 14]. Available from: https://merckindex.rsc.org/ 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. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) For external use only.When using this product avoid contact with the eyes and mucous membranes. If contact occurs, rinse thoroughly with water.Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist, worsen, or re-occur within a few days.Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy, rashes or burning discomfort occur (NIH 2023; 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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation		
Arnica montana	ArnicaArnica flowerEuropean arnicaLeopard's bane	Arnica montanaMountain arnicaMountain tobaccoWolf's	Flower	Dry
Arnica montana	Arnica tincture1	Arnica montana	Flower	Dry
Arnica montana	Oil of Arnica1	Arnica montana	Flower	Dry