Health Canada Santé Canada

NATURAL HEALTH PRODUCT

BURDOCK – *ARCTIUM LAPPA*
Topical

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(s)
Arctium lappa	• Burdock • Burr seed • Cocklebur • Edible burdock • Gobo • Goboshi • Great burdock • Great burdocks • Greater burdock • Hardock • Harebur • Lappa • Niu bang zi	*Arctium lappa*	Root	Dry

References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Brinker 2010; BHP 1996; Source information: BHP 1996;, Grieve 1971.

Route of administration

Topical

Dosage form(s)

Acceptable dosage forms when used according to the requirements indicated in this monograph: Cream; Gel; Liquid; Loose; Lotion; Ointment; Paste; Powder; Solution; Topical liquid; Wipe.

Use(s) or Purpose(s)

(Traditionally) used in Herbal Medicine to help relieve skin conditions such as eczema and psoriasis (Wichtl 2004; Bradley 1992; Williamson et al. 1988; Grieve 1971).

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., Burdock is traditionally used in Herbal Medicine to help relieve skin conditions such as eczema and psoriasis).
- 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)

Adults 18 years and older

Quantity(ies)

Notes:

- 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.,l mg/mL).
- For wipes, the information in this section applies to the liquid with which wipes are saturated.

Loose/Powder dosage forms

Methods of preparation: Dry, Powdered

100% of dried root (Grieve 1971).

Note: Products in loose or powder dosage forms must be prepared as an infusion by the consumer

prior to use (see direction for use).

Cream/Gel/Liquid/Lotion/Ointment/Paste/Solution/Topical liquid/Wipe dosage forms

Methods of preparation: Dry, Powdered, Fluid extract

5 – 8 % of dried root or dried root extract preparation in the finished product (Grieve 1971).

Note: For fluid extracts, the extract ratio must be 1:1 and the solvent must be ethanol or a mix of ethanol and water.

Methods of preparation: Non-Standardized Liquid Extracts (Decoction, Decoction concentrate, Infusion, Infusion concentrate, Tincture)

10 – 100% dried root extract preparation in the finished product (Grieve 1971).

Note: The extract ratio must be between 1:2 and 1:20. The formulation must be prepared in a way which is equivalent to a quantity of 50 to 80 milligrams crude dried root for 1 gram of finished product. For example, for a tincture prepared with a 1:10 w/v ratio, the concentration of tincture in the finished product must be between 50 and 80% (50 – 80 mg crude dried root = 0.05 – 0.08 g crude dried root * 10 w/v (dilution) = 0.5 – 0.8 mL liquid extract in 1 mL finished product = 50 – 80% v/v extract preparation in the finished product).

Methods of preparation: Non-Standardized Dry Extracts (Extract dry)

0.5 – 8% dried root extract in the finished product (Grieve 1971).

Notes:
- The extract ratio must be between 2:1 and 16:1. The formulation must be prepared in a way which is equivalent to a quantity of 50 to 80 milligrams crude dried root for 1 gram of finished product. For example, for a dry extract prepared with a 2:1 w/w ratio, the concentration of extract in the finished product must be between 2.5 and 4% (50 – 80 mg crude dried root / 2 w/w (concentration) = 25 – 40 mg dry extract in 1 g finished product = 2.5 – 4% w/w extract preparation in the finished product).
- The minimum quantity of 0.5% still applies for more concentrated extracts (e.g., a product containing 0.5% of a dry extract contains 5 mg dry extract in 1 g finished product; 5 mg of a 16:1 w/w dry extract is equivalent to 80 mg crude dried root).
- Solvents allowed for this method of preparation are ethanol and/or water.

Direction(s) for use

Loose/Powder dosage forms

Place [insert volume to be measured by consumer in order to obtain 4 to 6 grams dried root, e.g., 1 teaspoon] of product in 1/2 cup (125 mL) of water, boil down to 1/3 cup (80 mL). Let cool. Soak a small towel/pad/gauze/cotton in the product. Apply to affected area(s), up to 3 times per day (Hoffman 2003; Williamson et al. 1988; Grieve 1971).

Liquid dosage forms (Liquid, Solution, Topical liquid)

Soak a small towel/pad/gauze/cotton in the product. Apply to affected area(s), up to 3 times per day (Hoffman 2003; Williamson et al. 1988; Grieve 1971).

Cream/Gel/Lotion/Ointment/Paste/Wipe dosage forms

Apply to affected area(s), up to 3 times per day (Hoffman 2003; Grieve 1971).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- **For external use only.**
- **Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if** you are pregnant or breastfeeding (Brinker 2010; Barnes 2007).
- **When using this product** avoid contact with eyes and mucous membranes. If contact occurs, rinse thoroughly with water.
- **Ask a health care practitioner/health care provider/health care professional/doctor/ physician if** symptoms persist or worsen.
- **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 occurs (Brinker 2010).

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.

Product Facts
Medicinal ingredient (v/v) *Articum lappa* (Burdock) 1:X (liquid) extract XX % Equivalent to YY g dried root per 1 mL of product
Uses Traditionally used in Herbal Medicine to help relieve skin conditions such as eczema and psoriasis.
Warnings
For external use only
Ask a health care practitioner before use if you are pregnant or breastfeeding.
When using this product avoid contact with eyes and mucous membranes. If contact occurs, rinse thoroughly with water.
Stop use if allergy occurs.
Ask a health care practitioner if symptoms persist or worsen.
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.
Directions Adults 18 years and older: • Soak a small towel/pad in the product • Apply to affected area, up to 3 times per day.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

References cited

Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3rd edition. London (UK): Pharmaceutical Press; 2007.

BHP 1996: British Herbal Pharmacopoeia. Bournemouth (UK): The British Herbal Medicine Association; 1996.

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association; 1992.

Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.

Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication].

Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Raton (FL): Taylor and Francis Group; 2013.

Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003.

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 June 5]. 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 (D): Medpharm GmbH Scientific Publishers; 2004.

Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988.

References reviewed

Bisset NG, Wichtl M, editors. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 2nd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2001.

Gruenwald J, Brendler T, Jaenicke C, editors. PDR for Herbal Medicines, 1st edition. Montvale (NJ): Medical Economics Company; 1998.

Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005.

Peirce A. The American Pharmaceutical Association Practical Guide to Natural Medicines. New York (NY): William Morrow and Company, Inc; 1999.