Health Canada Santé Canada

NATURAL HEALTH PRODUCT

LUNGWORT – *PULMONARIA OFFICINALIS*
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)
Pulmonaria officinalis	• Bloody-butcher • Boys-and-girls • Hundreds-and-thousands • Jerusalem cowslip • Jerusalem-sage • Joseph-and-Mary • Lungwort • Mary-spilt-the-milk • Soldiers-and sailors • Spotted-dog	*Pulmonaria officinalis*	Leaf	Dry

References: Proper name: USDA 2024; Common names: USDA 2024; Gardner and McGuffin 2013; Source information: Williamson 2003; BHP 1983.

Route of administration

Topical

Dosage form(s)

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

Use(s) or Purpose(s)

Used in Herbal Medicine (as a vulnerary) to help heal minor wounds (such as cuts) (Williamson 2003; BHP 1983; Lust 1974).

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

Methods of preparation: Dry, Powdered, Fluid Extract

25 – 100% dried leaves (Williamson 1988; BHP 1983).

Notes:

- For fluid extracts, the extract ratio must be 1:1 and the solvent must be ethanol or a mix of ethanol and water.
- Products in loose or powder dosage forms must be prepared as an infusion by the consumer prior to use (see direction for use).

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

50 – 100% dried leaves extract preparation in the finished product (Williamson 1988; BHP 1983).

Note: The extract ratio must be between 1:2 and 1:4. The formulation must be prepared in a way which is equivalent to a minimum of 250 milligrams crude dried leaves per 1 gram of finished product. For example, for a tincture prepared with a 1:2 w/v ratio, the concentration of tincture in the finished product must be at least 50% (250 mg crude dried leaves * 2 w/v (dilution) = 0.5 mL liquid extract in 1 mL finished product = 50% v/v extract preparation in the finished product).

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

1.25 – 50% dried leaves extract preparation in the finished product (Williamson 1988; BHP 1983).

Notes:

- For dry extracts, the extract ratio must be between 2:1 and 20:1. The formulation must be prepared in a way which is equivalent to a minimum of 250 milligrams crude dried leaves per 1 gram of finished product. For example, for a dry extract prepared with a 4:1 w/w ratio, the concentration of dry extract in the finished product must be at least 6.25% (250 mg crude dried leaves / 4 w/w (concentration) = 62.5 mg dry extract in 1 g finished product = 6.25% w/w extract preparation in the finished product).
- Solvents allowed for this method of preparation are ethanol and/or water.

Direction(s) for use

Loose/Powder dosage forms

Prepare as a paste by mixing leaves with a small amount of water until you achieve the desired consistency. Apply to affected area(s), up to 3 times per day (Williamson et al. 2003; BHP 1983).

Liquid dosage forms (Liquid, Topical liquid, Solution)

Soak a small towel/pad/gauze/cotton in the product. Apply to affected area(s), up to 3 times per day (Williamson et al. 2003; BHP 1983).

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

Apply to affected area(s), up to 3 times per day (Williamson et al. 2003; BHP 1983).

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 eyes. 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 worsen or last (for) more than 7 days.
- **Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

Contraindication(s)

Do not use on deep or puncture wounds, animal bites or serious burns.

Known adverse reaction(s)

No statement required.

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 (w/w) *Pulmonaria officinalis* (Lungwort) X:1 extract XX % Equivalent to YY mg dried leaf per 1 g of product
Uses Used in Herbal Medicine to help heal minor wounds such as cuts.
Warnings
For external use only
Do not use on deep or puncture wounds, animal bites or serious burns.
When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.
Stop use and ask a health care practitioner if symptoms worsen or last more than 7 days.
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: 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

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