

FIGWORT

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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.

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Proper name(s): *Scrophularia nodosa* L. (Scrophulariaceae) (USDA 1997)

Common name(s):

- ▶ Figwort (McGuffin et al. 2000; USDA 1997)
- ▶ Common figwort (USDA 1997)

Source material(s): Aerial parts (Hoffmann 2003; BHP 1983)

Route(s) of administration: Oral

Dosage form(s):

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s): Statement(s) to the effect of:

- ▶ Traditionally used in Herbal Medicine as a diuretic (Hoffmann 2003; Felter and Lloyd 1983 [1898]; Wren 1907).
- ▶ Traditionally used in Herbal Medicine as an analgesic (anodyne) (Bartram 1995; Felter and Lloyd 1983 [1898]; Wren 1907).

- ▶ Traditionally used in Herbal Medicine to relieve symptoms of chronic cutaneous diseases (Hoffmann 2003; Wren 1907), eczema, psoriasis and pruritus (Hoffmann 2003; BHP 1983).
- ▶ Traditionally used in Herbal Medicine as a mild laxative (Hoffmann 2003; Williamson et al. 1988; Mills 1985)

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

Dose(s): Preparations equivalent to 0.2-8 g dried aerial parts, per day (Hoffmann 2003; Bartram 1995; BHP 1983; Felter and Lloyd 1983 [1898])

See Appendix 1 for examples of appropriate dosage preparations and frequencies of use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use:

Diuretic: For occasional use only (Berardi et al. 2002; CPA 2002).

Other uses: 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.
- ▶ Consult a health care practitioner prior to use if you are pregnant or breastfeeding.
- ▶ Consult a health care practitioner prior to use if you have heart disease (Hoffmann 2003; Brinker 2001).

Contraindication(s): No statement required.

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current *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*.

Note: Information detailed in this section is not to be submitted with the PLA, although it may be requested at Health Canada's discretion.

References cited:

Bartram T. Bartram's Encyclopedia of Herbal Medicine. New York (NY): Marlowe and Company; 1998.

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BHP 1983: British Herbal Pharmacopoeia. Cowling (GB): British Herbal Medical Association; 1983.

Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

CPA 2002: Canadian Pharmacists Association. Patient Self-Care. Helping Patients Make Therapeutic Choices. Ottawa (ON): Canadian Pharmacists Association; 2002.

Felter HW, Lloyd JU. King's American Dispensary, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

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

Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

Mills S. The Dictionary of Modern Herbalism. Wellingborough (GB): Thorsons Publishers Ltd; 1985.

USDA 1997: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). National Germplasm Resources Laboratory, Beltsville (MD). [*Scrophularia nodosa* L.: Last updated 1997-03-26; Accessed 2011-01-25]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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

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References reviewed:

Gruenwald J, Brendler T, Jaenicke C, editors. PDR for Herbal Medicines. 2nd edition. Montvale (NJ): Medical Economics Co.; 1998.

Appendix 1: Examples of dosage preparations and frequencies of use

Infusion: 2-8 g dried aerial parts, per day (BHP 1983)

Fluidextract:

- ▶ 1-2 g dried equivalent, 3 times per day (1:1, 1-2 ml) (Bartram 1995)
- ▶ 2-8 g dried equivalent, per day (1:1, 25% ethanol, 2-8 ml) (BHP 1983)
- ▶ 1.8-3.6 g dried equivalent, per day (1:1, 1.8-3.6 ml, (30-60 drops)) (Felter and Lloyd 1983 [1898])

Tincture:

- ▶ 0.4-0.8 g dried equivalent, three times per day (1:5, 40% ethanol, 2-4 ml) (Hoffmann 2003)
- ▶ 0.2-0.4 g dried equivalent, per day (1:10, 45% ethanol, 2-4 ml) (BHP 1983)
- ▶ 0.3-1.2 g dried equivalent, per day (Felter and Lloyd 1983 [1898]) (1:2, 76% ethanol, 0.6-2.4 ml, (10-40 drops))