



NATURAL HEALTH PRODUCT

BITTER FENNEL

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 and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date: July 18, 2017

Proper name(s):

Foeniculum vulgare Mill. subsp. *vulgare* var. *vulgare* (Apiaceae) (EMEA 2007a; EMEA 2007b; USDA 2006)

Common name(s):

Bitter fennel (EMEA 2007a; EMEA 2007b; USDA 2006)

Essential oil:

Bitter fennel essential oil

Source material(s):

Seed (EMEA 2007a,b)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.



Dosage forms by age group:

- **Children 4-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giaccoia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults \geq 18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

Use(s) or Purpose(s):

All source materials:

Traditionally used in Herbal Medicine as an expectorant to help relieve coughs associated with colds (EMEA 2007a; EMEA 2007b)

Seed:

- ▶ Traditionally used in Herbal Medicine to help relieve digestive disturbances including bloating and flatulence (EMEA 2007a).
- ▶ Traditionally used in Herbal Medicine to help relieve the pain associated with menstruation (EMEA 2007a).

Dose(s):

Seed:

Subpopulation:

Adults, adolescents, and children \geq 4 years (EMEA 2007a)

Quantity:

Adults, and adolescents \geq 13 years:

Infusion: 1.5-2.5 g comminuted (crushed) seed, 3 times per day (EMEA 2007a)

Children and adolescents 4-12 years:

Infusion: 1-1.7 g comminuted (crushed) seed, 3 times per day (EMEA 2007a)

Directions for use (for infusion):

Pour 250 ml (1 cup) of boiling water over seed and infuse for 15 minutes (EMEA 2007a).



Essential oil:

Subpopulation:

Adults \geq 18 years (EMEA 2007b)

Quantity:

Preparations equivalent to 0.2 ml essential oil, per day (EMEA 2007b)

Duration of use:

Adults, and adolescents \geq 13 years:

Consult a health care practitioner for use beyond 2 weeks (EMEA 2007a; EMEA 2007b).

Children and adolescents 4-12 years:

Consult a health care practitioner for use beyond 1 week (EMEA 2007a).

Risk information:

Caution(s) and warning(s):

All source materials:

- ▶ Consult a health care practitioner if symptoms persist or worsen.
- ▶ Consult a health care practitioner prior to use if you are pregnant or breastfeeding (EMEA 2007a; EMEA 2007b).

Essential oil:

Consult a health care practitioner prior to use if you are taking oral contraceptives, hormone therapy, hormone replacement therapy or other medications or natural health products (EMEA 2007b).

Contraindication(s):

Do not use if you are allergic to anethole or plants of the Apiaceae/Carrot family (EMEA 2007a; EMEA 2007b).

Known adverse reaction(s):

Hypersensitivity (e.g., allergy) has been known to occur (rare cases); in which case, discontinue use (EMEA 2007a; EMEA 2007b).

Non-medicinal ingredients:

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

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.
- ▶ The medicinal ingredient may comply with the specifications outlined in the Bitter Fennel or Bitter-Fennel Fruit Oil Monographs published in the European or British Pharmacopoeias.

References cited:

EMA 2007a. European Medicines Agency. Community Monograph on *Foeniculum vulgare* Miller subs. *vulgare* var. *vulgare*. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 5 July 2007. [Accessed 2008-03-19]. Available from: http://www.emea.europa.eu/pdfs/human/hmpc/foeniculi_amari_fructus/13742806enfin.pdf

EMA 2007b. European Medicines Agency. Community Monograph on *Foeniculum vulgare* Miller subs. *vulgare* var. *vulgare* oil. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 5 July 2007. [Accessed 2008-03-19]. Available from: http://www.emea.europa.eu/pdfs/human/hmpc/foeniculi_amari_fructus_aetheroleum/2632906enfin.pdf

EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Next link will take you to another Web site Formulations of choice for the paediatric population. Adopted September 2006. EMA/CHMP/PEG/194810/2005. [Accessed on 2013 June 29].

Giacoa GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101.

USDA 2006: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Foeniculum vulgare* Miller subs. *vulgare* var. *vulgare*. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2008-03-19]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl.