



NATURAL HEALTH PRODUCT

BITTER FENNEL- *FOENICULUM VULGARE*

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

October 30, 2018

Proper name(s), Common name(s), Source information

Bitter fennel crushed seed

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)
<i>Foeniculum vulgare</i> <i>subsp. vulgare var.</i> <i>vulgare</i>	<ul style="list-style-type: none"> ▶ Bitter fennel ▶ Common fennel 	<i>Foeniculum vulgare</i> <i>subsp. vulgare var.</i> <i>vulgare</i>	Seed	Dried and crushed

References: Proper name: USDA 2018, EMEA 2007a, EMEA 2007b; Common names: USDA 2018, EMEA 2007a, EMEA 2007b; Source information: EMEA 2007a, EMEA 2007b.

Bitter fennel essential oil

Table 2. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
<i>Foeniculum vulgare</i> <i>subsp. vulgare var.</i> <i>vulgare</i>	Bitter fennel essential oil	<i>Foeniculum vulgare</i> <i>subsp. vulgare var.</i> <i>vulgare</i>	Seed

References: Proper name: USDA 2018, EMEA 2007a, EMEA 2007b; Source information: USDA 2018, EMEA 2007a, EMEA 2007b.



Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

Children 4-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giaccoia et al. 2008; EMEA/CHMP 2006).

Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

All products (seed and essential oil)

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

Seed (except essential oil)

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

The following combined use(s) or purpose(s) is/are also acceptable:

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

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.



Dose(s)

ESSENTIAL OIL

Subpopulation(s)

Adults 18 years and older (EMEA 2007b)

Quantity(ies)

Method of preparation: Oil, Essential (water steam distillation)

0.2 millilitres of essential oil, per day (EMEA 2007b)

SEED

Subpopulation(s)

Children 4-11 years, Adolescents 12-17 years and Adults 18 years and older (EMEA 2007a)

Quantity(ies)

Methods of preparation: Dry, Infusion

Children 4-11 years

3-5 grams of comminuted (crushed) dried seed, per day; Not to exceed 1.6 grams per single dose (EMEA 2007a)

Adolescents 12-17 years and adults 18 years and older

4.5-7.5 grams of comminuted (crushed) dried seed, per day; Not to exceed 2.5 grams per single dose (EMEA 2007a)

Note: Comminuted (crushed) dried seeds should be prepared as an infusion (see direction for use).

Direction(s) for use

Dried seeds

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



Duration(s) of use

Children 4-11 years

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 1 week (EMEA 2007a).

Adolescents 12-17 years and adults 18 years and older

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 2 weeks (EMEA 2007a; EMEA 2007b).

Risk information

Caution(s) and warning(s)

All products

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician 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)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (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.

Storage conditions

No statement required.

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.

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), 6 August 2007. [Accessed 2018 August 15]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2009/12/WC500018464.pdf

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Giacoaia 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 2018: 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 2018 August 13]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl