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):


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 (Giaocia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 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 ≥ 4 years (EMEA 2007a)

**Quantity:**

Adults, and adolescents ≥ 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:


