



## NATURAL HEALTH PRODUCT

### SWEET 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

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>dulce</i>	<ul style="list-style-type: none"> <li>▶ Roman fennel</li> <li>▶ Sweet fennel</li> </ul>	<i>Foeniculum vulgare</i> <i>subsp. vulgare var.</i> <i>dulce</i>	Seed	Dried and crushed

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

#### Route of administration

Oral (EMEA 2007)

#### Dosage form(s)

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

#### 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)

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

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 2007).

### Note

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

### Dose(s)

#### Subpopulation(s)

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

#### Quantity(ies)

*Children 4-11 years*

Methods of preparation: Dry, Infusion

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

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

*Adolescents 12-17 years and Adults 18 year and older*

Methods of preparation: Dry, Powder, Non-Standardised Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

1.2 grams of comminuted (crushed) dried seed, per day; Not to exceed 0.4 grams per single dose



(EMEA 2007).

Methods of preparation: Dry, Infusion

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

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 2007).

### **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 2007).

#### *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 2007).

### **Risk information**

#### **Caution(s) and warning(s)**

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen (EMEA 2007).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (EMEA 2007).

#### **Contraindication(s)**

No statement required.

#### **Known adverse reaction(s)**

Stop use if hypersensitivity/allergy occurs (EMEA 2007).



## 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 2007. European Medicines Agency. Community Monograph on *Foeniculum vulgare* Miller. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 6 August 2007. [Accessed 2018 August 14]. Available from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Herbal\\_-\\_Community\\_herbal\\_monograph/2009/12/WC500018540.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_Community_herbal_monograph/2009/12/WC500018540.pdf)

EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. [Accessed 2018 June 1]. Available from: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003782.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf)

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. *dulce*. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 August 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>