Health Canada Santé Canada

SWEET FENNEL

Date: March 13, 2008

Proper name(s): *Foeniculum vulgare* Mill. subsp. *vulgare* var. *dulce* (Mill.) Batt. (Apiaceae) (EMEA 2007; USDA 2006)

Common name(s): Sweet fennel (EMEA 2007; USDA 2006)

Source material(s): Seed (EMEA 2007)

Route(s) of administration: Oral (EMEA 2007)

Dosage form(s): Those suited to the allowable route(s) of administration
This monograph is not intended to include 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 to help relieve digestive disturbances 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).

Dose(s):

Subpopulation: Adults, adolescents, and children ≥ 4 years (EMEA 2007)

Quantity:

Adults, and adolescents ≥ 13 years:

- Preparations equivalent to 0.4 g dried seed, 3 times per day (EMEA 2007)

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

Children and adolescents 4-12 years:

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

Directions for use (for infusion)**:**

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

Duration of use:

Adults, and adolescents ≥ 13 years:

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

Children and adolescents 4-12 years:

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

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

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

Contraindication(s): Do not use if you are allergic to anethole or plants of the Apiaceae/Carrot family (EMEA 2007).

Known adverse reaction(s): Hypersensitivity (e.g. allergy) has been known to occur (rare cases); in which case, discontinue use (EMEA 2007).

Non-medicinal ingredients: Must be chosen from the current NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

Specifications:

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- The medicinal ingredient may comply with the specifications outlined in the Sweet Fennel Monographs published in the European or British Pharmacopoeias.

References cited:

EMEA 2007. European Medicines Agency. Community Monograph on *Foeniculum vulgare* Miller. London (UK): EMEA Committee on Herbal Medicinal Products (HMPC), 5 July 2007. [Accessed 2008-03-11]. Available from: http://www.emea.europa.eu/pdfs/human/hmpc/foeniculi_dulcis_fructus/26329306enfin.pdf

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. *dulce*. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2008-03-11]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl