Fennel, Bitter

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BITTER FENNEL- FOENICULUM VULGARE Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 49 KB) 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 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 on the label. Date November 29, 2024 Proper name(s), Common name(s), Source information Bitter fennel fruit/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) Foeniculum vulgare subsp. vulgare var. vulgare Bitter fennel Common fennel Foeniculum vulgare subsp. vulgare var. vulgare Fruit Seed 1 Dry References: Proper name: USDA 2024; EMA 2024; Common names: USDA 2024; EMA 2024; Source information: EMA 2024. 1 The term 'seed' for fennel is often used to refer to the dried fruit. 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) Foeniculum vulgare subsp. vulgare var. vulgare Bitter fennel essential oil Foeniculum vulgare subsp. vulgare var. vulgare Fruit Seed 1 References: Proper name: USDA 2024; EMA 2007; Source information: USDA 2024; EMA 2007. 1 The term 'seed' for fennel is commonly used to refer to the dried fruit. 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 (Giacoia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) All products (fruit/seed and essential oil) (Traditionally) used in Herbal Medicine as an expectorant to help relieve coughs associated with colds (EMA 2024, 2007). Fruit/Seed (except essential oil) (Traditionally) used in Herbal Medicine to help relieve digestive upset including bloating and flatulence (EMA 2024). (Traditionally) used in Herbal Medicine to help relieve the pain associated with menstruation (EMA 2024). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help relieve the pain associated with menstruation and digestive upset including bloating and flatulence). Does not apply to the essential oil as only one claim is associated with it. For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Bitter fennel is traditionally used in Herbal Medicine as an expectorant to help relieve coughs associated with colds). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) ESSENTIAL OIL Subpopulation(s) Adults 18 years and older (EMA 2007). Quantity(ies) Method of preparation: Oil, Essential (water steam distillation) 0.2 milliliters of essential oil, per day (EMA 2007). FRUIT/SEED Subpopulation(s) Adults 18 years and older (Bradley 2006). Quantity(ies) Methods of preparation: Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) 0.6 - 2.8 grams of dried fruit/seed, per day (Bradley 2006; Hoffman 2003; Blumenthal 2000). Subpopulation(s) Children 4-11 years, Adolescents 12-17 years, Adults 18 years and older (EMA 2024). Quantity(ies) Methods of preparation: Dry 1 , Non-Standardized Aqueous Extracts (Dry extract, Infusion, Infusion concentrate) Children 4-11 years 3 - 5 grams of dried fruit/seed, per day; Not to exceed 1.6 grams per single dose (EMA 2024) Adolescents 12-17 years; Adults 18 years and older 4.5 - 7.5 grams of dried fruit/seed, per day; Not to exceed 2.5 grams per single dose (EMA 2024) 1 Note: Dried fruit/seed should be prepared as an infusion (see direction for use). Direction(s) for use Dried fruits/seeds Pour 250 ml (1 cup) of boiling water over fruit/seed and infuse for

15 minutes (EMA 2024). Combination rule No permitted combinations between the two medicinal ingredients listed in Tables 1 and 2. Duration(s) of Use Children 4-11 years Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 1 week (EMA 2024). Adolescents 12-17 years; Adults 18 years and older Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 2 weeks (EMA 2024, 2007). Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (EMA 2024, 2007). Essential oil and Tincture Ask a health care practitioner before use if you are taking any medications including birth control pills or hormone therapy or other health products (EMA 2007). Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (EMA 2024, 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 Must be established in accordance with the requirements described in the Natural Health Product Regulations . 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Blumenthal M, Goldberg A, Brinckman J, editors. Herbal Medicine: Expanded Commission E Monographs. Newton (MA): Integrative Medicine Communications; 2000. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association; 2006. EMA 2024. European Medicines Agency. Community Monograph on Foeniculum vulgare Miller subs. vulgare var. vulgare . London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 31 January 2024. [Accessed 2024 March 14]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-community-herbal-monograph-foeniculum-vulgare-miller-subsp-vulgare-var-vulgare-fructus_en.pdf EMA 2007. 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 2024 March 1]. Available from: http://www.e-lactancia.org/media/papers/Fennel-DS-EMEA2007.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 2024 March 14]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf Giacoia 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. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. USDA 2024: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 March 1]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

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 (Giacoia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:The acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.Ask a health care practitioner/health care

provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (EMA 2024, 2007). Essential oil and Tincture Ask a health care practitioner before use if you are taking any medications including birth control pills or hormone therapy or other health products (EMA 2007). Contraindication(s) No statement required. Known adverse reaction(s) Stop use if hypersensitivity/allergy occurs (EMA 2024, 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 Must be established in accordance with the requirements described in theNatural Health Product Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Product Regulations.

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. Example of Product Facts: Consult the Guidance Document,Labelling of Natural Health Productsfor more details.

REFERENCES

1The term 'seed' for fennel is often used to refer to the dried fruit. Bitter fennel essential oil Table 2. Proper name(s), Common name(s), Source informationProper name(s)Common name(s)Source informationSource material(s)Part(s)Foeniculum vulgare subsp. vulgare var. vulgareBitter fennel essential oilFoeniculum vulgare subsp. vulgare var. vulgareFruitSeed1 References: Proper name: USDA 2024; EMA 2007; Source information: USDA 2024; EMA 2007. 1The term 'seed' for fennel is commonly used to refer to the dried fruit. Route of Administration Oral

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Source material(s)	Part(s)		
Foeniculum vulgare subsp. vulgare var. vulgare	Bitter fennel essential oil	Foeniculum vulgare subsp. vulgare var. vulgare	FruitSeed1