

Egyptian Herbal Monograph

Volume 3

Medicinal Plants used in Egypt

Egyptian Drug Authority (EDA)

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***Foeniculum vulgare* Mill.**

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1. Names & Synonyms (1)

***Foeniculum vulgare* Mill.**

Family: Apiaceae (Umbelliferae).

Syns: *Anethum foeniculum* Clairv., *A. foeniculum* L., *A. rupestre* Salisb., *Feniculum commune* Bubani., *F. azoricum* Mill., *F. capillaceum* Gilib., *F. dulce* DC., *F. foeniculum* L. H. Karst., *F. officinale* All., *F. panmorium* DC., *F. piperitum* DC., *F. sativum* Bertol., *Ligusticum divaricatum* Hoffmannsegg et Link, L., *Foeniculum* Crantz., *Meum foeniculum* L. Spreng., *Ozodia foeniculacea* Wight et Arn., *Selinum foeniculum* L. E.H.L.Krause.

Arabic: Shamar شمر

English: Fennel.

2. Parts used for medicinal purposes

Dried ripe fruits (2).

3. Major chemical constituents

-**Essential oil:** *trans*-anethole (+)-fenchone, estragole (methylchavicol), limonene, *p*-anisaldehyde, α -pinene and α -phellandrene.

-**Phenolic acids:** rosmarinic acid and caffeoylquinic acid derivatives.

-**Flavonoids:** eriodictyol-7-rutinoside, quercetin-3-rutinoside.

- **Others:** triterpenes, smaller terpenes (monoterpenoids, sesquiterpenoids and diterpenoids) and reducing sugars (3).

4. Medicinal uses (Indications)

- A. Symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence (2,5).
- B. Symptomatic treatment of minor spasm associated with menstrual periods (2,5).
- C. Expectorant in cough associated with cold (2,4,5).

5. Herbal preparations correlated to medicinal use (6)

1. Whole or comminuted dried ripe fruits (freshly comminuted fennel fruits) in herbal tea bags with 0.25 L of boiling water (brew for 15 minutes).
2. Fennel powder.
3. Fennel liquid extract, using water as solvent.
4. Fennel dry extract, using mixture of ethanol and water in different concentrations as solvent.
5. Fennel oil.

Herbal preparations (2-5) are in pharmaceutical dosage forms. The pharmaceutical form should be described by the pharmacopoeia full standard term.

6. Posology and method of administration

Generally

Doses in adolescents (12 years and older) are the same as in adults (18 years and older) doses (2, 5, 7).

Duration of use: Not to be taken for more than two weeks for adults and adolescents (2, 4, 7) and one week for children. (7-8).

Children: To be used under medical supervision, for short-term use in mild transitory symptoms only (2, 4, 7).

Fennel is possibly safe for up to one week when used at appropriate doses (7).

Due to safety concerns regarding estragole, the daily amount of estragole must be adjusted to the body weight of the age group as estragole/day

Acceptable daily intake of estragole/day = 10 µg x body weight (kg) (9).

Preparation 1

Indication A, B

i) **Adults and adolescents:** 1.5 to 2.5 g three times daily as an herbal tea (2, 5, 7).

ii) **Children:**

- **Above 4 years of age:** Average daily dose: 3-5 g (2, 5, 7) in three divided doses (2, 7).
- **>1-4 years of age:** Average daily dose 1.5-3 g in three divided doses (2, 5).
- **0-1 year of age:** Average daily dose 1-2 g in three divided doses (5).

Preparation 2

Indication A, B

Adults: 5-7 g daily (6).

Preparation 3**Indication A, B, C**

i) Adults: 3-6 ml daily (6).

ii) Children: An aqueous preparation of average daily dose of equivalent crushed fruits, calculated as follows (5):

Above 4 years of age: 3-5 g.

- **1-4 years of age:** 1.5-3 g.
- **0-1 year of age:** 1-2 g.

Preparation 4**Indication A, B, C****Adults:**

- The appropriate dose depends on several factors such as the users age, health, and several conditions.
- Relevant directions on product labels should be followed and physician or pharmacist should be consulted before use.

Preparation 5**Indication A, C**

Adults: 0.2 ml of essential oil, as a single dose per day or in multiple divided doses (4,7).

Children: Pure essential oil should not be given to infants and young children (1) but it may be used in a pharmaceutical dosage form, under medical supervision and not exceed the appropriate dose

(The acceptable daily intake of estragole/day NMT $10 \mu\text{g} \times \text{body weight of the child (kg)}$) (9).

Method of administration: Oral use (2,4,5,7).

7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Pharmaceutical preparations containing 0.05gm fennel oil are contraindicated in children under the age of 1 year (10).

8. Special warnings and precautions for use

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted
- In rare cases, allergic reactions such as asthma, contact dermatitis and rhinoconjunctivitis have been reported in sensitive patients (1).

- Patients with known hypersensitivity to Asteraceae (Compositae) should avoid the use of fennel and its preparations because of cross reactivity risk (2).
- The pure essential oil from the fruits may cause inflammation and has an irritant action on the gastrointestinal tract (1).
- Bleeding disorders: Fennel might slow blood clotting, taking fennel might increase the risk of bleeding or bruising in people with bleeding disorders (8).
- Because of its estrogenic activity, excessive doses of fennel oil may affect hormone therapy, oral contraceptive pill and hormone replacement therapy (8).
- For children under 4 years of age fennel oil should be used under medical supervision (2).
- The pure essential oil should not be given to infants and young children without medical supervision owing to the danger of laryngeal spasm, dyspnea and central nervous system excitation (1,11).

9. Interactions with other medicinal products and other forms of interaction

Anticonvulsants: Fennel may increase the risk of seizures; avoid concurrent use (6).

Ciprofloxacin: Fennel affects the absorption, distribution, and elimination of ciprofloxacin. If the two are used concurrently, their dosages should be separated by at least 2 hours (6,8,12).

10. Fertility, pregnancy and lactation

-Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy or lactation is not recommended (2,4).

-Fennel fruit may be used during pregnancy and lactation at the recommended dosage, as infusions only (5).

- No fertility data available.

11. Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

12. Undesirable effects

- If adverse reactions occur, a doctor or a pharmacist should be consulted.

-**Allergic reactions to fennel**, affecting the skin or the respiratory system may occur (6).

- Hypersensitivity reactions, contact dermatitis, photosensitivity (6).
- Pulmonary edema, possible hormone-sensitive cancers (6).

-**Allergic reactions to fennel oil**, affecting the skin, the respiratory and gastrointestinal system, seizures, hallucinations, nausea, vomiting or anorexia may occur (6).

13. Overdose

No case of overdose has been reported (2,4).

14. Relevant biological properties

Not required as per Egyptian guidelines for registration of herbal medicines.

15. Additional information

-There are two varieties of fennel fruit: bitter fennel (*Foeniculi amari fructus*) and sweet fennel (*Foeniculi dulcis fructus*) (5).

- Bitter fennel is richer in essential oil than sweet fennel (5).

16. Date of compilation/last revision

19/07/2022.

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