

Egyptian Herbal Monograph

Volume 3

Medicinal Plants used in Egypt

Egyptian Drug Authority (EDA)

2024



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***Pimpinella anisum* L.**

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1. Names & Synonyms (1)

***Pimpinella anisum* L.**

Family: Apiaceae (Umbelliferae).

Syns: *Anisum officinarum* Moench., *A. vulgare* Gaertn., *Apium anisum* L. Crantz., *Carum anisum* L. Baill., *Pimpinella anisum* cultum Alef., *P. aromatica* Bieb., *Selinum anisum* L. E.H.L. Krause., *Sison anisum* Spreng., *Tragium anisum* Link.

Arabic: Yansoon ينسون

English: Anise, Aniseed.

2. Parts used for medicinal purposes

Dried ripe fruits (1).

3. Major chemical constituents

Essential oil: contains mainly trans-anethole, estragole (methylchavicol, isoanethole), β -anisaldehyde, α -terpenol, *cis*-anethole (1).

4. Medicinal uses

A. Symptomatic treatment of mild, spasmodic gastrointestinal complaints including dyspepsia, bloating and flatulence (2, 3).

B. Expectorant in cough associated with cold and inflammation of respiratory tract (2-4).

5. Herbal preparations correlated to medicinal use (3)

1. **Comminuted herbal substance as herbal tea for oral use as an infusion.**

Whole or comminuted dried ripe fruits (freshly comminuted) with 0.25L. of boiling water (brew for 15 minutes).

2. **Anise powder.**

3. **Anise dry extract**, using mixture of ethanol and water in different concentrations as solvent.

4. **The essential oil.**

Herbal preparations (2-4) are in pharmaceutical dosage forms. The pharmaceutical form should be described by the pharmacopoeia full standard term.

6. Posology and method of administration (2)

Generally

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

Duration of use: Not to be taken for more than two weeks for adults and adolescents (2).

Due to safety concerns regarding estragole, the daily amount of estragole must be adjusted to the body weight of the age group as acceptable daily intake of estragole/day = $10 \mu\text{g} \times \text{body weight (kg)}$ (6).

Preparation 1

Adults and adolescents: 1 to 3.5 g of the whole or (freshly comminuted or crushed) aniseed in 150 ml of boiling water as a herbal infusion 3 times daily (2).

Children (5):

- **0-1 year of age:** average daily dose of 0.5 g of crushed fruits as an infusion.
- **> 1-4 years of age:** average daily dose of 1 g of crushed fruits as an infusion.
- **4-10 years of age:** average daily dose of 2 g of crushed fruits as an infusion.

Preparation 2

Adults: 3 g powder taken after each meal three times daily for 4 weeks for treatment of dyspepsia (7,8).

- For a long-term disorder of the large intestines that causes stomach pain (irritable bowel syndrome or (IBS)): 200 mg of anise oil in a special coated capsule, to be taken three times daily for 4 weeks (7).

- Menopausal symptoms 330 gm to be taken 3 times daily for 4 weeks (8).

Preparation 3

Adults:

-The appropriate dose depends on several factors such as the user's age, health, and several conditions.

-Relevant directions on product labels should be followed and physician or pharmacist should be consulted before use (9).

Preparation 4

Adults: 0.05-0.2 ml of anise oil, three times daily (10).

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 (**Estragole/day NMT 10µg/kg/day x body weight of the child kg**) (6).

Method of administration: Oral use (2).

7. Contraindications

Hypersensitivity to active substances and to other plants of the same family (2,9).

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

-Anise might lower blood sugar, so blood sugar levels should be monitored carefully if diabetic patients use anise (7).

- The use in children under the age of 12 years is not recommended without medical supervision (1,2).

-Anise oil should not be given to children and adolescents under age of 18 years due to the presence of estragole and physician advice should be sought (1-3).

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

- **Estrogens, hormonal contraceptives:** large quantities of anise may interfere with estrogen replacement therapy or hormonal contraceptives (theoretical). Some types of cancer are affected by hormones in the body. Estrogen-sensitive cancers are cancers that are affected by estrogen levels in the body (3,7,9).

- **Iron:** Anise may increase the action of iron (3).

- **Warfarin:** Anise may increase the action of warfarin (3).

- **Lab Test:** Increased Prothrombin time (PT/INR) (3).

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).

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

-Owing to the traditional use of the oil as an emmenagogue and to induce labour, its experimental estrogenic and potential mutagenic effects, and reports of anethole toxicity in infants (2).

-No fertility data available but there are a mild oestrogenic activity and antifertility effects of the essential oil and anethole (the major constituent of the essential oil) (5).

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 aniseed affecting the skin or the respiratory system may occur (1-3).
- Occasional allergic reactions to the oil affecting the skin, respiratory system and gastrointestinal tract are reported e.g. nausea and vomiting (1,3).
- Hypermineralocorticism (3).

13. Overdose

- Ingestion of 1.0–5.0 ml of the oil can result in nausea, vomiting, seizures and pulmonary edema (1,3).
- Anethole toxicity in infants has been reported, and presents clinically with symptoms of hypertonia, continued crying, atypical ocular movements, twitching, cyanosis, vomiting and lack of appetite (1).
- In cases of overdose (> 50 mg/kg), the ingestion of milk and alcohol is contraindicated owing to increased resorption (1).

14. Relevant biological properties

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

15. Additional Information

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16. Date of compilation/last revision

20/8/2023.

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