

Egyptian Herbal Monograph

Volume 3

Herbal Formulations used in Egypt

Egyptian Drug Authority (EDA)

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Anise oil, Peppermint oil

زيت ينسون / زيت نعناع

1. Names & Synonyms

Anise (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.

Peppermint (2)

***Mentha piperita* L.**

Family: Lamiaceae.

Arabic: Ni'na نعناع

English: Peppermint.

2. Parts used for medicinal purpose

Anise oil: Dried ripe fruits (1).

Peppermint oil: Fresh overground parts and the dried leaves (2-4).

3. Major chemical constituents

Anise oil:

Trans-anethole, estragole (methylchavicol, isoanethole), β -anisaldehyde, α -terpenol and *cis*-anethole (1).

Peppermint oil:

Menthol, menthone, menthyl acetate, menthofuran and 1,8- cineole (eucalyptol) (5).

4. Medicinal uses (Indications)

Symptomatic treatment of digestive disorders such as dyspepsia (indigestion) flatulence, bloating, minor spasms of the gastrointestinal tract and abdominal pain especially in irritable bowel syndrome (2-4, 6,7).

5. Herbal preparations correlated to medicinal use

Combination of Anise oil and Peppermint oil.

Herbal preparation is in solid pharmaceutical gastro-resistant dosage form. The pharmaceutical form should be described by the pharmacopoeia full standard term.

6. Posology and method of administration correlated to medicinal use

Adults and elderly:

- 20 mg of Anise oil and 50 mg of Peppermint oil, 3 times daily.
- 100 mg of Anise oil and 56 mg of Peppermint oil, once daily.
- 150 mg of Anise oil and 30 mg of Peppermint oil 1-3 times daily.

Duration of Use:

- Not to be taken for more than 2 weeks.
- If symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted.

Method of administration: Oral use.

Should be taken 30-60 minutes before meals and to be swallowed whole, not broken or chewed (7).

7. Contraindications

- Hypersensitivity to the active substances and to other plants of the same family.
- Patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders (3,6-8).

8. Special warnings and precautions for use (7)

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- The use in children and adolescents under 18 years of age is not recommended.
- Patients who already suffer from heartburn or hiatal hernia, have sometimes an exacerbation of this symptom after taking peppermint oil. Treatment should be discontinued in these patients.

- The product should be used with caution in inflamed and ulcerated conditions of the gastrointestinal tract.
- Other medicinal products containing peppermint oil should be avoided during the use of this product.
- The gastro-resistant solid dosage forms should be swallowed whole, i.e., not broken, or chewed, because this would release the peppermint oil prematurely, possibly causing local irritation of the mouth and oesophagus.

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

- Concomitant use of food or antacids could cause early release of the content the medicinal product (7).
- Other medicinal products used to decrease stomach acid, such as histamine-2 blockers and proton pump inhibitors may cause premature dissolution of the gastro-resistant solid dosage form and should be avoided (7).

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 (3, 7, 9).
- No fertility data available (7).

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.
- Urine and stools with an odour of menthol, dysuria and inflammation of the glans of the penis (7).
- Occasional allergic reactions to the skin, respiratory system and gastrointestinal tract are reported e.g. nausea and vomiting (2,4,7).
- Allergic reactions to menthol (bradycardia, muscle tremor, ataxia, anaphylactic shock, headache and erythematous skin rash may occur (7).
- Heartburn, perianal burning, blurred vision and dry mouth (7).

13. Overdose

- Overdose may cause severe gastrointestinal symptoms: diarrhoea, rectal ulceration; epileptic convulsions, loss of consciousness, apnoea, nausea, vomiting, pulmonary edema and disturbances in cardiac rhythms, ataxia and other CNS problems (1,6-7).
- In the case of overdose, the ingestion of milk and alcohol is contraindicated owing to increased resorption (1). The stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment, if necessary (7).

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

20/08/2023.

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