

Egyptian Herbal Monograph

Volume 2

Medicinal Plants used in Egypt

Egyptian Drug Authority (EDA)

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Mentha piperita L.

نعناع

1. Names & Synonyms (1)

Mentha piperita L.

Family: Lamiaceae.

Arabic: Ni'na نعناع

English: Peppermint.

2. Parts used for medicinal purpose

The fresh overground parts and the dried leaves (1-3).

3. Major chemical constituents

- **Essential oils:** Menthol, menthone, menthyl acetate, menthofuran, and 1,8-cineole (eucalyptol) (4).
- **Flavonoids:** Luteolin, luteolin-7-O-glucoside, naringenin-7-O-glucoside, isorhoifolin, eriodictyol, eriocitrin glycoside and apigenin (5).

4. Medicinal uses (Indications)

- A. Symptomatic treatment of digestive disorders such as dyspepsia, flatulence, minor spasms of the gastrointestinal tract, abdominal pain and irritable bowel syndrome (1-3, 6,7), gastritis and indigestion (1,2,7).
- B. Relief of symptoms in coughs and colds (1,8).
- C. Symptomatic relief of mild tension type headache (1,8).
- D. Symptomatic relief of localised muscle pain (8).
- E. Symptomatic relief of localised pruritic conditions in intact skin (8).

5. Herbal preparations correlated to medicinal use

1. Comminuted herbal substance as herbal tea for oral use in the form of infusion (3, 6).
2. Herbal substance or the comminuted herbal substance is added to 100-150 ml of boiling water as herbal infusion (3, 6).
3. Tincture, (1:5, 45% ethanol (3, 6) or 70% ethanol (6)).
4. Essential oil (1, 2, 7, 8).

Herbal preparations (2,3) are in pharmaceutical dosage forms. The pharmaceutical form should be described by the pharmacopoeia full standard term.

- The internal solid dosage form should be in enteric coated form (gastric resistant) (1, 7, 8).
- Liquid form should be in diluted preparations or suspensions (1).

6. Posology and method of administration correlated to medicinal use

Preparation 1

Indication A

Adults and elderly: 1.5-3 g as oral infusion, 3 times daily (3, 6).

Children from 4 years and adolescents: 1-2g, 3 times daily (3, 6).

Preparation 2

Indication A

Adults and elderly: 2-3 ml, 3 times daily (3, 6).

Duration of use (6)

If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a pharmacist should be consulted.

Method of administration: Oral use (6).

Preparation 3

Indication A (1, 8)

Adolescents, adults and elderly: 0.2–0.4 ml essential oil, 2 or 3 times daily in solid gastro-resistant dosage forms, diluted preparations or suspensions.

Children from 8 to 11 years of age: 0.2 ml in solid gastro-resistant dosage forms 3 times daily.



Duration of use (8)

The gastro-resistant dosage forms should be taken until symptoms resolve, usually within one or two weeks. At times when the symptoms are more persistent, the intake of gastro-resistant dosage forms can be continued for periods of no longer than 3 months per course.

Method of administration (8): Oral use.

The gastro-resistant dosage forms must be taken whole 30 minutes before meals.

Indication B

Oral use in lozenges or oromucosal use in oral spray (8):

Adolescents, adults and elderly: 0.08-0.12 ml essential oil, 3-4 times per day (8).
2-10 mg essential oil per lozenge (1).

Inhalation:

The essential oil is added to hot water and the vapour is inhaled (8).

Adolescents, adults and elderly: 0.08-0.16 ml of essential oil up to 3 times daily (8).
3-4 drops essential oil in hot water (1).

Cutaneous use (8):

Adolescents, adults and elderly: Nasal ointments 1-5%, up to 3 times daily.

Cutaneous and transdermal use (8):

Apply a thin layer on the chest, on the back or around the nostrils.

Adults and elderly:

- Semi-solid and oily preparations 5-20%.
- Hydroethanolic preparations 5-10%.

Up to 3 times daily.

Adolescents:

- Semi-solid preparations 5-15%.
- Hydroethanolic preparations 3-6%.

Up to 3 times daily.

Children from 4 to 11 years of age:

- Semi-solid preparations 2-10%.
- Hydroethanolic preparations 2-4%.

Up to 3 times daily.

Duration of use

If the symptoms persist longer than two weeks during the use of the medicinal product, a doctor or pharmacist should be consulted.



Indication C (8)

Adults and elderly: In liquid or semi-solid preparations 10% in ethanol.

The treatment consists of one application, which can be repeated two times at 15 minutes intervals, once daily.

Method of administration: Cutaneous use.

The preparation should be rubbed on the skin of the forehead and temples.

Indication D, E (8)

Cutaneous and transdermal use: Apply a thin layer on the affected area.

Adults and elderly:

- Semi-solid and oily preparations 5-20%.
 - Hydroethanolic preparations 5-10%.
- Up to 3 times daily.

Adolescents:

- Semi-solid preparations 5-15%.
 - Hydroethanolic preparations 3-6%.
- Up to 3 times daily.

Children from 4 to 11 years of age:

- Semi-solid preparations 2-10%.
 - Hydroethanolic preparations 2-4%.
- Up to 3 times daily.

Duration of use

- It is not recommended to use the medicinal product continuously for more than two weeks.
- If the symptoms persist longer than two weeks during the use of the medicinal product, a doctor or a pharmacist should be consulted.

7. Contraindications

Hypersensitivity to active substances and to other plants of the same family.

(Oral use of peppermint leaf preparations) (6):

- Patients with gastroesophageal reflux (heartburn) because it can worsen the case.
- The use in children under 4 years of age is not recommended.

(Oral use of oil):

- Patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders (2,7-9).
- Peppermint oil should not be given internally to children (2, 7).

- Children under 2 years of age, because menthol can induce reflex apnoea and laryngospasm (8).
- Children with history of seizures (febrile or not) (8).

(Topical use of oil):

- Peppermint oil should not be used topically on the face, particularly near the nose, or on infants or small children (7, 9).
- Children under 2 years of age, because menthol can induce reflex apnoea and laryngospasm (8).
- Children with history of seizures (febrile or not) (8).

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.

Oral use of peppermint leaf preparations (6):

Patients with gallstones and any other biliary disorders should be cautious in using peppermint leaf preparations.

Use of oil (8):

- Other medicinal products containing peppermint oil should be avoided during the use of this medicinal product.
- Eye contact with unwashed hands after the application of peppermint oil may potentially cause irritation.

o Oral use for the symptomatic relief of digestive disorders (8):

- 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.
- 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 use of peppermint oil in children under 8 years of age is not recommended.

o Cutaneous use for the symptomatic relief of mild tension type headache (8):

- The use in children and adolescents under 18 years of age is not recommended.

o Inhalation, cutaneous (nasal application), oral (as lozenges) and oromucosal use (as oral spray) for relief of symptoms in coughs and colds:

- Peppermint oil should be used with caution in inflamed and ulcerated conditions of the gastrointestinal tract (8).

- Patients with gallstones and any other biliary disorder should be cautious using peppermint oil (8).
- The use in children between 2 and 11 years of age is not recommended (1,8).
- o **Cutaneous and transdermal use for relief of symptoms in coughs and colds, for the symptomatic relief of localized muscle pain and for the symptomatic relief of localized pruritic conditions in intact skin:**
 - Peppermint oil should not be applied on broken or irritated skin (8).
 - The use is not recommended in children below 4 years of age (8).

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

- Use of food or antacids administered at the same time of oral use of the peppermint oil for the symptomatic relief of digestive disorders could cause early release of the capsule content (8).
- Other medicinal products used to decrease stomach acid, such as histamine-2 blockers and proton pump inhibitors may cause premature dissolution of the enteric coating and should be avoided (8).
- Cytochrome P450 3A4 substrate: Peppermint oil may decrease drugs metabolized by cytochrome P450 3A4 substrates (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 and lactation is not recommended (2,6,8).
- No fertility data available (6,8).

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 (6,8).

12. Undesirable effects

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

Peppermint leaves:

- Nausea, anorexia, increased indigestion with hiatal hernia, exacerbation of biliary colic, bronchospasm (7), gastroesophageal reflux may worsen and heartburn may increase (8).

Peppermint oil:**o Inhalation**

- Apnoea, broncho- and laryngo-constriction in hypersensitive patients have been reported (8).

o Oral and oromucosal use

- Urine and stools with an odour of menthol were observed; dysuria and inflammation of the glans of the penis have been reported (8).
- Allergic reactions to menthol were reported, with bradycardia, muscle tremor, ataxia, anaphylactic shock (8), flushing, mucous membrane irritation, urticaria (7) headache and erythematous skin rash (7,8).
- Heartburn, nausea (7,8), vomiting, perianal burning blurred vision and dry mouth (8).

o Cutaneous and transdermal use (8)

- Hypersensitivity reactions such as skin rash, contact dermatitis, and eye irritation have been reported.
- Irritation of the skin and mucosa of the nose is possible, after local application.

13. Overdose

Peppermint leaves: No case of overdose has been reported (9).

Peppermint oil (8):**o Inhalation**

Inhalation of large doses of menthol may lead to dizziness, confusion, muscle weakness, nausea and double vision.

o Oral and oromucosal use

- Overdose may cause severe gastro-intestinal symptoms, diarrhoea, rectal ulceration, epileptic convulsions, loss of consciousness, apnoea, nausea and disturbances in cardiac rhythms, ataxia and other CNS problems, probably due to the presence of menthol.
- In the event of overdose, the stomach should be emptied by gastric lavage. Observation should be carried out with symptomatic treatment if necessary.

o Cutaneous and transdermal use

No case of overdose has been reported.

14. Relevant biological activities

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



15. Additional Information

The amount of pulegone and menthofuran has to be specified in the given product. The daily exposure has to be below 37.5 mg per person. For children, the daily exposure has to be below 0.75 mg/kg b.w. per day (10).

16. Date of compilation/last revision

14/06/2022.

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