



هَيْئَةُ الدَّوَاءِ الْمَصْرِ بِيَّة

Volume **3**

# Egyptian Herbal Monograph

## Medicinal Plants Used *in Egypt*



Bearberry



# Egyptian Herbal Monograph

## Volume 3

# Medicinal plants used in Egypt

Egyptian Drug Authority (EDA)

2022



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## Acknowledgment

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### **Members of the Specialized Scientific Committee of Herbal Medicines:**

- Prof. Dr. Mervat Ahmed Fouad*      *Consultant of pharmacognosy and special foods- National Nutrition Institute (NNI). Head of Codex committee on spices and culinary herbs-Egyptian organization for standardization and quality. Member of the Technical Harmonization Committee (TCH 82) in African Organization for Standardization (ARSO). Former member of the evaluation committee of Egyptian Guidelines for Registration of Herbal Medicines.*
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## Preface

Since 2020, EDA has published two volumes of the Egyptian herbal monograph on Egyptian wild medicinal plants. The first volume includes thirteen monographs of wild medicinal plants used traditionally in Egypt and the second one contains additional seven monographs of wild medicinal plants mentioned in the Egyptian Pharmacopoeia. Both of these volumes are now available on the EDA website <http://www.edaegypt.gov.eg/>

The third volume is considered as continuation of the previous volumes of the Egyptian herbal monograph but consists of sixteen monographs of cultivated medicinal plants used in Egypt. These monographs are intended to serve as a guide for the preparation of the scientific file of the herbal medicinal product needed upon registration for market authorization as they provide scientific information on the safety, efficacy, quality, appropriate use of the medicinal plants and facilitate registration procedures. It is anticipated that this monograph will be updated in the near future.

*Egyptian Drug Authority (EDA)*

2022



# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Anethum graveolens* L.

شبت

### 1. Names & Synonyms (1)

*Anethum graveolens* L.

**Syns:** *Pastinaca anethum* Spreng., *Peucedanum graveolens* Benth. & Hook.,  
*Selinum anethum* Roth.

**Family:** Apiaceae (Umbelliferae).

**Arabic:** Shabat شبت

**English:** Dill.

### 2. Parts used for medicinal purposes

Dried ripe fruits (1).

### 3. Major chemical constituents

**Essential oil:** carvone, limonene,  $\alpha$ -phellandrene, dihydrocarvone, dillapiole (2),  
1,8-cineole,  $\alpha$ -pinene and  $\alpha$ -terpene (1).

### 4. Medicinal uses (Indications)

- A. Carminative and spasmolytic in infantile colic (3).
- B. For dyspepsia, gastritis, flatulence, stomachache (1) and as antispasmodic (4).

### 5. Herbal preparations correlated to medicinal use

- 1. Dill oil (as Dill water for infants) (5).
- 2. Dill oil (1,3,6).

3. Dill dry extract (using mixture of ethanol and water in different concentrations as solvent).
4. Dill powder (1,4,6).

**Herbal preparations are in a pharmaceutical dosage form. The pharmaceutical form should be described by the pharmacopoeia full standard term.**

## 6. Posology and method of administration

### Preparation 1(5)

#### Indication A

Dill water for infants: only for babies from 1 to 12 months old.  
(Each 5 ml contain 2.3 mg dill water):

- 1-6 months old: 2.3 mg one teaspoonful during or after a feed.
- 6-12 months old: 2 teaspoonful during or after a feed.

Don't use more than 6 times in 24 hours.

### Preparation 2-4

#### Indication B

#### Preparation 2

- **Adults:** Dill oil: 0.05-2 ml (3 times daily) (3,6) or 0.1-0.3 g daily in divided doses (1,3,6).
- **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 should not exceed the appropriate dose.

#### Preparation 3

-The appropriate dose of the extract depends on several factors such as the user's age, health, and several other conditions (7,8).

- Consult your physician or pharmacist before using (7,8).

#### Preparation 4

3 gm or equivalent (for other preparations) (1,4,6).

**Method of administration:** oral use.

## 7. Contraindications

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

## 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
- Dill should not be given to children except under medical supervision (6).
- Persons with a fluid or electrolyte imbalance should not use this herb (6).
- Diabetes:** Dill extract might lower blood sugar in people with diabetes so blood sugar level should be monitored regularly (7,8).
- Surgery:** Stop taking Dill extract at least 2 weeks before a scheduled surgery because dill extract might interfere with blood sugar control medications during and after surgery (7,8).
- Underactive thyroid** (hypothyroidism): Taking Dill as a medicine seems to lower thyroid hormone levels. This might worsen symptoms in people with underactive thyroid (8).

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

None reported.

## 10. Fertility, pregnancy and lactation

- Dill should not be used during pregnancy and breastfeeding (1,6-8).
- Dill extract has been used as a contraceptive and to induce labour.
- Dill extract may have teratogenic effects (1).
- Dill can start menstruation and this might lead to a miscarriage (7,8).
- 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.
- May alter sodium balance and allergic reaction (6).

## 13. Overdose

No case of overdose has been reported.

## 14. Relevant biological properties

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

## 15. Additional Information

- There are two type of dill oil (dill seed oil & Terpenless dill seed oil).
- Terpenless dill seed oil is richer in carvone than dill seed oil.

## 16. Date of compilation/last revision

25/03/2022

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5	<a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a>
6	Mosby's Handbook of Herbs and Natural Supplements. 4 <sup>th</sup> ed., ISBN: 978-0-323-05741-7.
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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Arctostaphylos uva-ursi* L.

عنب الدب

### 1. Names & Synonyms (1)

*Arctostaphylos uva-ursi* L.

**Family:** Ericaceae.

**Syns.:** *Arbutus uva-ursi* L., *Arctostaphylos media* Greene, *Arbutus officinalis* Wimm., *Arbutus procumbens* Patzke, *Mairania uva-ursi* Desv., *Uva-ursi buxifolia* S.F. Gray, *Uva-ursi procumbens* Moench.

**Arabic:** Enab eddib عنب الدب

**English name:** Bearberry, Uva ursi.

### 2. Parts used for medicinal purpose

Dried leaves (1-4).

### 3. Major chemical constituents

**-Hydroquinone derivatives:** Arbutin and methyl-arbutin (glycosides); galloyl arbutin, and hydroquinone (2, 5).

**-Flavonoids:** Myricetin, quercetin and their glycosides including hyperin, isoquercitrin, myricitrin and quercitrin; hyperoside; kaempferol (2,5,6).

**-Polyphenols:** Gallotannins, corilagin, catechin, anthocyanidin derivatives including cyanidin and delphinidin (2).

**-Phenolic acids:** Gallic, *p*-coumaric and syringic, salicylic acid, *p*-hydroxybenzoic, ferulic, caffeic and lithospermic acids (dimeric caffeic acid) (2).

**-Terpenoids:**  $\alpha$ -Amyrin,  $\alpha$ -amyrin acetate,  $\beta$ -amyrin, lupeol, uvaol, ursolic acid, and a mixture of mono- and di-ketonic  $\alpha$ -amyrin derivatives (1,2,5).

#### 4. Medicinal Uses (Indications)

Symptomatic treatment of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent urination in women, after serious conditions have been excluded by a medical doctor (1-3).

#### 5. Herbal preparations correlated to medicinal use (2)

1. Comminuted herbal substances as herbal tea for oral use.

1.5-4 g (4) of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion or a macerate (1,4).

2. Powdered herbal substance.

3. Dry extract, extraction solvent ethanol 60% V/V, containing 23.5-29.3% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry).

4. Dry extract, extraction solvent water, containing 20-28% of hydroquinone derivatives calculated as anhydrous arbutin (spectrophotometry).

5. Liquid extract, extraction solvent ethanol 25% V/V.

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

#### 6. Posology and method of administration correlated to medicinal use (2)

##### Adult and elderly females

1. 2 to 4 times daily. Maximum daily dose: 8 g.

The macerate should be used immediately after preparation.

2. Single dose: 700 – 1050 mg, twice daily. Maximum daily dose: 1.75 g.

3,4. Single dose: the dose corresponding to 100–210 mg of hydroquinone derivatives calculated as anhydrous arbutin, 2–4 times daily.

Daily dose: the dose corresponding to 200–840 mg of hydroquinone derivatives calculated as anhydrous arbutin (3).

5. Single dose: 1.5–4 ml, up to 3 times daily. Maximum daily dose: 8 ml.

**Duration of use:**

- Not to be used for more than one week.
- If the symptoms persist for more than 4 days during the use of the medicinal product, a doctor or a pharmacist should be consulted.

**Method of administration:** oral use (1-3).

## 7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Kidney disorders (2).
- During pregnancy or lactation (1,3).
- Children under the age of 12 years (1,4), as hepatotoxicity may occur (4).

## 8. Special warnings and precautions for use

- If the symptoms worsen or if complaints such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, a doctor or a pharmacist should be consulted (2,3).
- It should not be used for prolonged periods (1-4).
- It should be used cautiously by persons with electrolyte imbalance, acidic urine, constipation, iron deficiency, anemia, malnutrition due to high tannin level, and disorders involving gastrointestinal irritation (4).
- It should not be administered with medicines or foods that acidify the urine, such as acidic fruits or fruit juice and should be administered with plenty of fluids (1,3).
- It may cause a greenish-brown coloration of the urine (1,2) that darkens on exposure to air due to the oxidation of hydroquinone (1).
- The use in children and adolescents under 18 years of age is not recommended without medical advice (2).
- The use in men is not recommended without medical supervision (2).

## 9. Interactions with other medicinal products and other forms of interaction (4)

- Concurrent use with diuretics can lead to electrolyte loss, primarily hypokalemia.
- Uva ursi may increase the effect of NSAIDs.
- Urine acidifiers may inactivate Uva ursi; concurrent use should be avoided.

## 10. Fertility, pregnancy and lactation

- The use during pregnancy and lactation should be avoided (1,4).
- No fertility data available (2).

## 11. Effects on ability to drive and use machines (2)

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

## 12. Undesirable effects (2)

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Nausea, vomiting and stomachache.

## 13. Overdose (4)

Hepatotoxicity, cyanosis, tinnitus, vomiting, seizures, cardiovascular collapse, delirium, shortness of breath and feeling of suffocation.

## 14. Relevant biological activities

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

## 15. Additional Information

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## 16. Date of compilation/last revision

24/6/2022



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3	Natural Health Product – Bearberry - <i>Arctostaphylos uva-ursi</i> L. (2019). Health Canada, <a href="http://webprod.hc-sc.gc.ca/nhp/bdipsn/atReq.do?atid=arctostaphylos.uva.ursi&amp;lang=eng">http://webprod.hc-sc.gc.ca/nhp/bdipsn/atReq.do?atid=arctostaphylos.uva.ursi&amp;lang=eng</a>
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6	Sugier, P., Sęczyk, Ł., Sugier, D., Krawczyk, R., Wójcik, M., Czarnecka, J., Okoń, S., and Plak, A. (2021). Chemical characteristics and antioxidant activity of <i>Arctostaphylos uva-ursi</i> L. Spreng. at the southern border of the geographical range of the species in Europe. <i>Molecules</i> , 26(24), 7692. <a href="https://doi.org/10.3390/molecules26247692">https://doi.org/10.3390/molecules26247692</a>

# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Carum carvi* L.

كراوية

### 1. Names & Synonyms (1)

*Carum carvi* L.

**Syns.** *Carum velenovskyi* Rohlena.

**Family:** Apiaceae (Umbelliferae).

**Arabic:** karawya كراوية

**English:** Caraway.

### 2. Parts used for medicinal purpose

Dried fruits (2, 3).

### 3. Major chemical constituents

- **Essential oil:** mainly carvone and limonene (5).
- **Fatty acids:** mainly unsaturated fatty acids as petroselinic, linoleic and oleic acids beside saturated fatty acids as myristic and palmitic acids (5, 6).
- **Flavonoids:** quercetin, kaempferol and their glycosides (quercetin-3-glucuronides, quercetin 3-*O*-caffeoylglucoside and kaempferol 3-glucoside) and isoquercitrin (5, 7).
- **Protein** (5).

### 4. Medicinal uses (Indications)

- A. For the symptomatic relief of digestive disorders such as bloating, flatulence, and digestive spasms (2, 4).
- B. To aid digestion and help stimulate appetite (stomachic) (8).
- C. For relief of flatulent colic in infants and children (3).

## 5. Herbal preparations correlated to medicinal use

1. Herbal substance or comminuted herbal substance as herbal tea for oral use (2).

0.5-2 g of the herbal substance or comminuted herbal substance in 150 ml of boiling water as herbal infusion (2).

2. Liquid extract (8).
3. Dry extract (8).
4. Essential oil (3, 4, 8).

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

## 6. Posology and method of administration correlated to medicinal use

### Preparation 1

#### Indications A, B

**Adults:** herbal tea for oral use 1-3 times daily (2).

### Preparation 2, 3

#### Indications A, B

The equivalent extract of the following amount of the dried fruit (g/day) (8):

Adults 18 years and older	0.3-15 g
Adolescents 12-17 years	0.3-15 g
10-11 years	0.3-15g
4-9 years	0.3 -4 g
Children 1-3 years	0.3 -2 g
Infants 6-12 months	0.06 -1 g

### Preparation 4

#### Indications A, B

#### Oral (3, 9):

- \* **Adults 18 years and older:** 3 – 6 drops (0.15-0.3 ml) (4) in divided doses daily.
- \* **Children above 4 years:** 3 – 6 drops daily.
- \* **Children 1-3 years:** 2 – 4 drops daily.
- \* **Children up to 1 year:** 1-2 drops daily.

## Indication C

### External (3, 4):

\* **Children and adolescents:** an ointment (2% w/w) to be applied once daily in the evening as a thin layer on the abdominal area after bathing.

\* **Adults:** 10% in olive oil, rub 10-12 drops onto the stomach (10).

**Method of administration:** oral and cutaneous use (2, 3, 8).

## 7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- The use in patients with liver disease, cholangitis, achlorhydria, gallstones and any other biliary disorders are not recommended (4).
- The product should not be used on broken skin, around the eyes or on mucous membranes (4).
- Caraway should not be used in gastroesophageal reflux disease (11).

## 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 (2, 4).

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

None reported (2, 4).

## 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, 4, 8, 11).
- No fertility data available (2,4).

## 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 (2, 4).

## 12. Undesirable effects

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Anorexia, diarrhea, skin redness, irritation and contact dermatitis (11).

## 13. Overdose

An intake of over dose of the volatile oil for extended periods can lead to kidney and liver damage (11, 12).

## 14. Relevant biological activities

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

## 15. Additional Information

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## 16. Date of compilation/last revision

11/06/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Cucurbita pepo* L.

قرع عسل

### 1. Names & Synonyms (1)

*Cucurbita pepo* L.

**Syns:** *Cucurbita aurantia* Willd., *C. courgero* Ser., *C. esculenta* Gray, *C. fastuosa* Salisb., *C. melopepo* L., *C. ovifera* L., *C. subverrucosus* Willd., *C. verrucosus* L., *Pepo melopepo* Moench., *P. verrucosus* Moench., *P. vulgaris* Moench.

**Family:** Cucurbitaceae.

**Arabic:** kar-e-asal قرع عسل

**English:** Pumpkin.

### 2. Parts used for medicinal purposes

Dried seeds (1-3).

### 3. Major chemical constituents

-**Fixed oil:** composed mainly of linoleic, oleic, palmitic and stearic acids (4).

-**Phytosterols:**  $\beta$ -Sitosterol,  $\Delta^{5,24}$  - stigmastadienol,  $\Delta^7$ -stigmastenol,  $\Delta^7$ -avenasterol (5).

-**Phytoestrogens:** including lignans (as secoisolarisiresinol), isoflavones (as genistin, daidzin and formononetin) and quercetin (6).

-**Phenolic acids:** Protocatechuic, caffeic, syringic, vanillic, *p*-coumaric and ferulic acids (6).

-**Protein:** composed mainly of the amino acids: arginine, glutamic and aspartic acids (7).

-**Others:** Vitamin E (Tocopherols), micro-elements such as phosphorus, magnesium, potassium, zinc and iron (7) as well as  $\beta$ -carotene (8).

#### 4. Medicinal uses (Indications)

Relief of lower urinary tract symptoms related to benign prostatic hyperplasia (2, 3, 9-11) or related to an overactive bladder, after serious conditions have been excluded by a medical doctor (2,3).

#### 5. Herbal preparations correlated to medicinal use (2)

1. Comminuted herbal substance.
2. Soft extract, extraction solvent ethanol 92% m/m.
3. Dry extract, extraction solvent ethanol 60% v/v.
4. Pumpkin seed oil.

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

#### 6. Posology and method of administration correlated to medicinal use (2)

##### Adults and elderly:

1. Comminuted herbal substance, single dose: 2.5 – 7.5 g, 2 times daily.
2. Soft extract, single dose: 500 mg, 2 times daily.
3. Dry extract, single dose: 105 mg, 3 times daily or 152 mg, 2 times daily.
4. Pumpkin seed oil, single dose: 1 – 1.2 g, 3 times daily, daily dose: 3 - 4 g.

**Method of administration:** oral use.

#### 7. Contraindications (2)

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

#### 8. Special warnings and precautions for use (2)

- 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.

- If complaints worsen or if symptoms such as fever, spasms or blood in the urine, painful urination or urinary retention occur during the use of the medicinal product, a doctor or a pharmacist should be consulted.

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

**Diuretics:** Pumpkin may increase the action of diuretics; use together cautiously (11).

## 10. Fertility, pregnancy and lactation

- Pumpkin is prohibited in pregnancy (12).
- Safety during lactation has not been established. In the absence of sufficient data, the use during lactation is not recommended (2).
- No fertility data available (2).

## 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 (2).

## 12. Undesirable effects

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Gastric disorders (Vomiting, nausea, anorexia) (2).
- Pumpkin Seed oil: Hypersensitivity reactions and skin irritation have been observed (2).
- Electrolyte loss (sodium, potassium chloride) (11).

## 13. Overdose

No case of overdose has been reported (2).

## 14. Relevant biological properties

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

## 15. Additional Information

For benign prostatic hyperplasia (BPH): pumpkin seed oil could be used in combination with saw palmetto and other herbs (10).

## 16. Date of compilation/last revision

15/05/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Curcuma longa* L.

كركم

### 1. Names & Synonyms (1)

*Curcuma longa* L.

**Syns.** *Curcuma domestica* Valetton.,

**Family:** Zingiberaceae.

**Arabic:** Kurkum كركم

**English:** Turmeric.

### 2. Parts used for medicinal purpose

The dried rhizome (1-3).

### 3. Major chemical constituents (1)

**-Curcuminoids:** A mixture of curcumin, monodesmethoxycurcumin and bisdesmethoxycurcumin (1, 4).

**-Essential oil:** Composed of a number of monoterpenes and sesquiterpenes, including sesquiphellandrene, ar-turmerone, curcuminol, *cis*- $\beta$ -elemenone, zingiberene, curcumene,  $\alpha$ - and  $\beta$ - turmerone (1, 4, 5).

**-Others:** Acidic polysaccharides (4).

### 4. Medicinal uses (Indications)

- A. Relief of digestive disturbances, such as feelings of fullness, flatulence, acid dyspepsia and aid digestion (1-3).
- B. Antioxidant and Hepatoprotective (3).
- C. Relieve pain and inflammation due to rheumatoid arthritis and help relieve joint pain (1, 3).



## 5. Herbal preparations correlated to medicinal use (2)

1. Comminuted herbal substance as herbal tea for oral use.  
0.5-1.0g comminuted herbal substance in 150 ml of boiling water as an infusion (1, 2).
2. Powdered herbal substance (1)
3. Tincture (ratio of herbal substance to extraction solvent 1:10),  
extraction solvent ethanol 70% (V/V) (2)
4. Tincture (ratio of herbal substance to extraction solvent 1:5), extraction  
solvent ethanol 70% (V/V) (2)
5. Dry extract, extraction solvent ethanol 96% (V/V)
6. Dry extract, extraction solvent ethanol 50% (V/V)
7. Liquid extract, extraction solvent ethanol 45% (V/V) (6).

Herbal preparations (2-7) are in a pharmaceutical dosage form. The pharmaceutical form should be described by the pharmacopoeia full standard term.

## 6. Posology and method of administration correlated to medicinal use

### Indication A (2)

Adults and elderly:

**Preparation 1:** 0.5-1.0 g in 150 ml of boiling water as an infusion, 2-3 times daily (1, 2).

**Preparation 2:** 0.5-1 g, 2-3 times daily (2), 1.5–3.0g daily (1).

**Preparation 3:** 0.5-1 ml, 3 times daily (1, 2).

**Preparation 4 :** 10 ml once daily or 5 ml in 60 ml water, 3 times daily (2).

**Preparation 5:** 90-162 mg, divided in 2-5 doses daily (2).

**Preparation 6:** 100-200 mg, 2 times daily (2).

### Indication B

Adults and elderly:

**Preparation 7:** 5 -14 ml of 1:1 liquid extract, daily (6).

### Indication C

Adults and elderly:

**Preparation 1:** 0.5-1.0 g oral infusion 3 times daily.

**Preparation 2:** 1.5–3.0g daily (1).

**Preparation 3:** 0.5–1 ml 3 times daily (1).

**Duration of use** (2)

For indication A, 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 (2)

It should be taken on an empty stomach (7).

## 7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Due to possible stimulation on bile secretion *Curcuma longa* is not recommended in case of obstruction of the bile duct, cholangitis, liver disease, gallstones and any other biliary diseases (1-3).

## 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.
- The use in children and adolescents under 18 years of age is not recommended (1, 2).
- Coagulation studies should be monitored in the case of long-term treatment of turmeric (7).

## 9. Interactions with other medicinal products and other forms of interaction (7)

- Use of turmeric with anticoagulants, antiplatelets, NSAIDs and anticoagulant/antiplatelets herbs may result in an increased risk of bleeding. So, concurrent use should be avoided.
- Immunosuppressants (cyclosporine): Turmeric may decrease the effectiveness of immunosuppressants. So, concurrent use should be avoided.

## 10. Fertility, pregnancy and lactation (1, 2)

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

## 12. Undesirable effects

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Mild symptoms of dry mouth, flatulence, gastric irritation (2).
- Hypersensitivity reactions, including contact dermatitis (7).

## 13. Overdose

Gastrointestinal ulceration (7).

## 14. Relevant biological activities

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

## 15. Additional Information

-

## 16. Date of compilation/last revision

28/6/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Cynara cardunculus* L.

خرشوف

### 1. Names & Synonyms (1)

*Cynara cardunculus* L.

**Syns:** *Cynara scolymus* L.

**Family:** Asteraceae (Compositae).

**Arabic:** Kharshouf خرشوف

**English:** Artichoke, Globe Artichoke.

### 2. Parts used for medicinal purposes (1)

Fresh and dried leaves.

### 3. Major chemical constituents (2)

- **Phenolic acids:** Caffeic acid, chlorogenic acid (3-*O*-caffeoylquinic acid), cynarin (1,5-di-*O*-caffeoylquinic acid), 1-*O*-caffeoylquinic acid, 4-*O*-caffeoylquinic acid, 5-*O*-caffeoylquinic acid.

- **Sesquiterpene lactones:** Cynaropicrin, dehydrocynaropicrin, grosheimin and their derivatives.

- **Flavonoids:** Luteolin-7-*O*-rutinoside (scolymoside), luteolin-7-*O*-glucoside, and luteolin-4-*O*-glucoside, cynaroside and cynarotrioside.

- **Essential oil:** Consisting mainly of  $\beta$ -selinene and caryophyllene.

- **Phytosterols:** Taraxasterol.

#### 4. Medicinal uses (Indications)

- A. Symptomatic relief of digestive disorders such as dyspepsia with a sensation of fullness, bloating and flatulence (3).
- B. In [hyperlipidemia](#) (high levels of [fats](#)) (4).
- C. As choleric (increase bile flow) and hepatoprotective (4, 5).

#### 5. Herbal preparations correlated to medicinal use

- 1- Comminuted dried leaves for herbal tea as an infusion (3).  
Comminuted herbal substance in 150ml of boiling water as a herbal infusion.
- 2- Powdered dried leaves (3).
- 3- Dry extract of dried leaves, extraction solvent water (3).
- 4- Dry extract of fresh leaves, extraction solvent water (3).
- 5- Soft extract of fresh leaves, extraction solvent water (3).
- 6- Soft extract of dried leaves, extraction solvent ethanol 20% (V/V) (3).
- 7- Liquid extract (4, 6).

Herbal preparations (2-7) are in a pharmaceutical dosage form. The pharmaceutical form should be described by the pharmacopoeia full standard term.

#### 6. Posology and method of administration correlated to medicinal use

- 1- Comminuted dried leaves for herbal tea (3):
  - 1.5g of the herbal substance as a herbal infusion 4 times daily.
  - Or 3g of the herbal substance as a herbal infusion 1-2 times daily.
- 2- Daily dose: 600-1500g (in divided doses, 2-4 times a day) (3).
- 3- Daily dose: 400-1320mg in divided dose (3).
- 4- Daily dose: 600-2700mg in divided dose (3).
- 5- Daily dose: 600mg-1800 mg in divided dose (3).
- 6- Daily dose: 700 mg three times daily (3).
- 7- Daily dose: 3-8 ml three times daily (4, 6).

**Duration of use:** It is possibly safe when taken as a medicine for up to 12 weeks (7).

**Method of administration:** oral use (3).



## 7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Obstruction of bile duct (1, 3, 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.
- The use in children under 12 years of age is not recommended (3).
- The use in cholangitis, gallstones and any other biliary disorders require medical supervision and advice (3, 6, 8-10).
- Use cautiously in hepatic or renal diseases (9).

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

- Possible interaction with coumarin-type anticoagulants (1).
- Artichoke tea may interfere with the absorption of iron salts (9).
- Artichoke decreases blood glucose, taking artichoke along with diabetes medications might cause blood sugar to drop too low (7, 9).

## 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 (1, 3, 9, 10).
- 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.
- Gastrointestinal complaints included mild diarrhea, accompanied by abdominal cramps, upper abdominal pain, nausea, and heartburn (3, 7).

## 13. Overdose

No case of overdose has been reported (3).

## 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

28/3/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Foeniculum vulgare* Mill.

شمر

### 1. Names & Synonyms (1)

*Foeniculum vulgare* Mill.

**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.

**Family:** Apiaceae (Umbelliferae).

**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,  $\alpha$ -pinene and  $\alpha$ -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 a pharmaceutical dosage form. 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 =  $10 \mu\text{g} \times \text{body weight (kg)}$  (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 µg x 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

23/03/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Glycyrrhiza glabra* L.

عرقسوس

### 1. Names & Synonyms (1)

*Glycyrrhiza glabra* L. and its varieties or *Glycyrrhiza uralensis* Fisch.

**Syn.** *Liquiritae officinalis* Moench.

**Family:** Fabaceae (Leguminosae).

**Arabic:** Irksos, Erqsos عرقسوس

**English:** licorice, licorice root, liquorice, liquorice root, sweet root and sweet wood.

### 2. Parts used for medicinal purpose

Dried Root (1-4) and rhizome (1, 4).

### 3. Major chemical constituents (5)

- **Saponins:** Glycyrrhizin and glycyrrhizic acid (glycyrrhizinic acid), as a mixture of potassium and calcium salts.
- **Flavonoids:** glycosides of liquiritigenin and isoliquiritigenin, such as liquiritin, isoliquiritin, liquiritin apioside and licuraside (6).
- **Others:** Essential oil (mainly geraniol and geranyl hexanolate) and sterols ( $\beta$ -sitosterol, dihydrostigmasterol) (7).

#### 4. Medicinal uses (Indications)

- A. Relief of digestive symptoms including burning sensation and dyspepsia (2), inflammatory conditions, such as gastritis in adults (3).
- B. Expectorant in cough associated with cold (2, 3) to help relief chest complaints, such as mucous build up (catarrhs) and bronchitis (3).
- C. Relieve minor inflammations of mucous membranes of the mouth (such as canker sores) (demulcent) (3).

#### 5. Herbal preparations correlated to medicinal use (2)

1. Comminuted herbal substance as herbal tea for oral use in the form of infusion or decoction.  
1.5 - 2 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion or decoction.
2. Soft extract (1:0.4-0.5), extraction solvent water.
3. Soft extract (3:1), extraction solvent water.
4. Dry extracts that correspond to preparations mentioned under 2) and 3).
5. Deglycyrrhizinated (DGL) dry extract (3)
  - 5.1 Acceptable dosage forms for the age category listed in this monograph and specified route of administration are limited to chewables.
  - 5.2 In dosage forms suited to buccal administration which allow for contact between the affected tissue and the medicinal ingredient including but not limited to lozenges, chewables (e.g. gummies, tablets), strips and liquids (such as gargles, rinses).

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

## 6. Posology and method of administration correlated to medicinal use (2)

### Preparation 1-4

#### Indication A

##### Adults and elderly

1. 2 to 4 times daily. Take one cup after meals.
2. Soft extract (1: 0.4-0.5) 32 mg 2-3 times daily for oral use. Not more than 160 mg (32 mg 5 times) daily.
4. Doses of dry extracts are corresponding to preparation 2.

Not to be used for more than 4 weeks.

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

#### Indication B

##### Adults and elderly

1. 2 times daily. Take one cup after meals.
3. Soft extract (3:1) 1.2-1.5 g 3-4 times daily.
4. Doses of dry extracts corresponding to preparation 3.

If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or pharmacist should be consulted.

**Method of administration:** Oral use.

### Preparation 5.1

#### Indication A

##### Adults and elderly:

380 mg -1520 mg (3 times a day).

##### Adolescents:

**15-17 years:** 380 mg - 1520 mg (3 times a day).

**12-14 years:** 190 mg -760 mg (3 times a day).

**Children:**

**10-11 years:** 190 mg -760 mg (3 times a day).

**5-9 years:** 95 mg - 380 mg (3 times a day).

**3-4 years:** 63 mg -253 mg (3 times a day).

Chew between meals or 20 minutes before meals, 3 times a day.

**Method of administration:** oral use.

**Preparation 5.2**

**Indication C**

**Adults and elderly:**

200 mg -1140 mg (4 times a day).

**Adolescents:**

**15-17 years:** 200 mg - 1140 mg (4times a day).

**12-14 years:** 100 mg -570 mg (4 times a day).

**Children:**

**10-11 years:** 100 mg -570 mg (4 times a day).

**5-9 years:** 50 mg - 285 mg (4 times a day).

**3-4 years:** 33 mg -190 mg (4 times a day).

Gargle four times daily with 200 mg DGL powder dissolved in 200 ml of warm water, 4 times per day.

**Method of administration:** buccal use.

## 7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Cholestatic liver disorders, liver cirrhosis, hypertonia, hypokalemia, severe kidney insufficiency and cardiovascular-related disorder, because liquorice ingestion has resulted in symptoms of primary hyperaldosteronism, such as water and sodium retention and hypokalaemia (8).

## 8. Special warnings and precautions for use (2)

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- Patients taking licorice medication should not take other licorice containing products as serious adverse effects may occur such as water retention, hypokalemia, hypertension, cardiac rhythm disorders (4).
- Licorice medication is not recommended to be used in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia, as they are more sensitive to the adverse effects of licorice (4).
- If dyspnoea, fever or purulent sputum occurs, a doctor or pharmacist should be consulted

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

- Licorice root may counteract antihypertensive action of prescribed medications (2) and may cause increased hypokalemia (4).
- Not to be used concomitantly with diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance (2, 4, 9, 10).
- Azole antifungals: Licorice may increase the levels of azole antifungals; avoid concurrent use (3).
- Cytochrome P450 3A4, 2B6 substrates: Licorice may decrease the action of these agents (4).
- **Herb (4)**  
**Aloe (taken internally), buckthorn, cascara and chinese rhubarb:**  
Licorice may cause hypokalemia when used with stimulant laxative herbs.
- **Food (4)**  
**Grapefruit juice:** Use of licorice with grapefruit juice may increase corticosteroid action of licorice.
- **Lab Test (4)**  
**Anion gap, blood, potassium, serum prolactin, serum or urine sodium:**  
Licorice may decrease anion gap, blood; potassium (greater than 6 weeks); serum prolactin; serum or urine sodium results.  
**Serum, urine myoglobin:** Licorice may cause a possible positive test for serum, urine myoglobin.

## 10. Fertility, pregnancy and lactation

- The use during pregnancy and lactation should be avoided (8). Studies in animals have shown reproductive toxicity (2).
- No fertility data available (2).

## 11. Effects on ability to drive and use machines (2)

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

## 12. Undesirable effects

- None reported (2).
- If adverse reactions occur, a doctor or a pharmacist should be consulted.

## 13. Overdose

- Cases of overdose have been reported with prolonged use (more than 4 weeks) and/or intake of high amount of licorice, with symptoms such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy (2, 10) and in rare cases, myoglobinuria (10).
- Individuals consuming 10–45 g licorice/day have exhibited raised blood pressure, together with a block of the aldosterone/renin axis and electrocardiogram changes, which resolved one month after withdrawal of licorice. Individuals consuming vastly differing amounts of licorice have exhibited similar side-effect symptoms, indicating that the mineralocorticoid effect of licorice is not dose dependent and is a saturable process (8).

## 14. Relevant biological activities

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

## 15. Additional Information

A deglycyrrhizinated licorice (DGL) preparation has been developed to provide some of the therapeutic benefits of licorice while reducing risk. It is a form of licorice that people have processed for safer consumption. DGL, which as the name implies, removed its glycyrrhizinate content, making it safer to use this form of licorice than the former. This makes DGL safer for long-term use and has less interactions with



medical conditions. DGL contains less than 2% of glycyrrhizin, making it suitable as an alternative long-term treatment against conditions related to gastrointestinal problems such as peptic ulcers, canker sores, and reflux (GERD). DGL or Deglycyrrhizinated Licorice DGL, doesn't seem to have the same side effects.

Some people are so sensitive to glycyrrhizin that even the tiny amounts left in deglycyrrhizinated licorice can pose a problem.

DGL licorice although considered safer it may still pose certain health risks. You should also avoid DGL licorice if you have a history of diabetes, edema, high blood pressure, or heart, kidney or liver disease (11).

## 16. Date of compilation/last revision

14/06/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

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

**Herbal preparations (2,3) are in a pharmaceutical dosage form. 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.

### **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.

### **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.

### **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).

### **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:

#### ○ Inhalation

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

#### ○ 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).
- **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):**

- **Inhalation**

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

- **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.

- **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

20/06/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Pimpinella anisum* L.

ينسون

### 1. Names & Synonyms (1)

*Pimpinella anisum* L.

**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.

**Family:** Apiaceae (Umbelliferae).

**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),  $\beta$ -anisaldehyde,  $\alpha$ -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 a pharmaceutical dosage form. 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

**i) 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).

### ii) 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).

- Use of oil in pregnancy and nursing is contraindicated (2).

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

25/3/2022



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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

***Psidium guajava* L.**

جوافة

### 1. Names & Synonyms (1)

***Psidium guajava* L.**

**Syns.:** *Psidium aromaticum*, *P. cujavillus* Burm, *P. pomiferum*, *P. pyrifera*, *P. pumilum*.

**Family:** Myrtaceae.

**Arabic:** Gawafa جوافة

**English name:** Guava.

### 2. Parts used for medicinal purpose

Dried leaves (1).

### 3. Major chemical constituents

#### Phenolic Compounds (2)

- Flavonoids: Quercetin and its glycosides, avicularin, apigenin, guaijaverin, kaempferol, kaempferol-3-arabofuranoside, hyperin, myricetin, rutin, catechin, epicatechin, epigallocatechin gallate and proanthocyanidins.
- Phenolic acids: Gallic acid and caffeic acid.

#### Essential Oil (3,4)

$\beta$ -Caryophyllene, 4 $\alpha$ -selin-7 (11)-enol,  $\beta$ -caryophyllene oxide,  $\alpha$ -selinene,  $\beta$ -selinene,  $\delta$ -cadinene, daucol, cubenol, 1,8-cineole (eucalyptol) and aromadendrene.

#### Others (2)

Sugars: Sulphated and unsulphated polysaccharides (uronic acid), minerals (calcium, potassium, sulfur, sodium, iron, boron, magnesium, manganese and zinc), vitamins (C and B) and macronutrients (protein and fat).

#### 4. Medicinal Uses (Indications)

- A. Cough sedative (1-3, 5, 6).
- B. Antidiarrheal agent (1, 2, 7-9).
- C. For gingivitis and bleeding gum (1).

It is also reported to be used in certain gastrointestinal disorders as antispasmodic (2, 7-9) and in viral and infectious gastroenteritis (1,10).

#### 5. Herbal preparations correlated to medicinal use

- 1. Decoction (1,10).
- 2. Powdered drug (1).
- 3. Aqueous liquid extract (1).
- 4. Dry extract (10).

Herbal preparations (3 and 4) are in liquid and solid dosage forms, respectively. The pharmaceutical form should be described by the pharmacopoeia full standard term.

#### 6. Posology and method of administration correlated to medicinal use

##### Preparation 1

**Indication A:** The appropriate oral dose depends on several factors such as the user's age, health and other several conditions.

**Indication B:** Three times daily (10).

##### Preparation 2

**Indication B:** 500 mg of the powdered leaves to be taken orally 3-4 times daily (1).

##### Preparation 3

**Indication A:** The appropriate oral dose depends on several factors such as the user's age, health and other several conditions.

**Indication C:** 15 ml to be used externally as mouthwash 3 times daily for at least one minute per session (1).

#### **Preparation 4**

**Indication B:** 500 mg oral capsule containing powder dry extract every 8 hours for 3 days (10).

**Method of administration:** oral and external use.

#### **7. Contraindications**

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

#### **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.

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

None reported.

#### **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.
- 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**

- None reported.
- If adverse reactions occur, a doctor or a pharmacist should be consulted.

#### **13. Overdose**

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**

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#### **16. Date of compilation/last revision**

27/5/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

***Serenoa repens* (W.Bartram) Small**

بلميط منشاري

### 1. Names & Synonyms

***Serenoa repens* (W.Bartram) Small (1,2).**

**Syns:** *Corypha repens* W.Bartram, *Corypha obliqua* W.Bartram, *Diglossophyllum serrulatum* (Michx.) H. Wendl. ex Salomon, *Sabal serrulata* (Michx.) Schult.f., *Chamaerops serrulata* Michx., *Brahea serrulata* (Michx.) H. Wendl. (1,2).

**Family:** Arecaceae (1,2).

**Arabic:** Balmit minshary بلमित منشاري

**English:** *Serenoa*, Saw palmetto (3) and Saw palmetto berry (4).

### 2. Parts used for medicinal purpose

Dried ripe fruit (5).

### 3. Major chemical constituents (6)

**Fatty acids and their glycerides:** Monoacylglycerides (1-monolaurin, 1-monomyristicin). Oleic acid (unsaturated) and capric acid, caproic acid, caprylic acid, lauric acid, myristic acid, palmitic acid and stearic acid (saturated).

**Steroids:**  $\beta$ -Sitosterol, campesterol and stigmasterol.

**Carbohydrates:** Invert sugar, mannitol, high molecular weight polysaccharides with galactose, arabinose and uronic acid identified as main sugar components.

**Other constituents:** Flavonoids (e.g. rutin, isoquercitrin, kaempferol), pigment (carotene), resin, tannin and volatile oil.

### 4. Medicinal Uses (Indications)

Symptomatic treatment of benign prostatic hyperplasia; relief of lower urinary tract symptoms (7, 8).

## 5. Herbal preparations correlated to medicinal use (7)

1. Soft extract, extraction solvent: hexane.
2. Soft extract, extraction solvent: ethanol 90% to 96% m/m.

**Herbal preparations are in a pharmaceutical 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

320 mg, once daily or 160 mg, 2 times daily (7).

### Duration of use

Long-term use, up to 6 months, is possible (7,9).

Typically, symptom reduction is experienced within 1–2 months' treatment (3).

If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted (7).

**Method of administration:** oral use (7).

## 7. Contraindications

Hypersensitivity to the active substances and to other plants of the same family (7).

## 8. Special warnings and precautions for use

If complaints worsen or if symptoms such as fever, spasms or blood in the urine, painful urination, or urinary retention occur during the use of the medicinal product, a doctor or a pharmacist should be consulted (7).



## 9. Interactions with other medicinal products and other forms of interaction (7)

A few cases of suspected interactions with warfarin have been reported. Increased INR- values have been described.

## 10. Fertility, pregnancy and lactation (7)

- Pregnancy and lactation: not relevant.
- No fertility data available.

## 11. Effects on ability to drive and use machines (7)

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

## 12. Undesirable effects (7)

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Abdominal pain, nausea, vomiting, diarrhea, abdominal pain (especially when taken on an empty stomach), allergic or hypersensitivity reactions may occur such as skin rash, headache, increase of transaminases or gamma-glutamyl transferases and reversible gynecomastia.

## 13. Overdose (7)

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

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## 16. Date of compilation/last revision

24/6/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

***Thymus vulgaris* L.**

زعرور

### 1. Names & Synonyms

***Thymus vulgaris* L. (1)**

**Syns.:** *Origanum thymus* Kuntze, *Thymus collinus* Salisb.

**Family:** Lamiaceae (Labiatae).

**Arabic:** Za'ater زعرور

**English name:** English Thyme, Garden Thyme.

***Thymus zygis* L. (2)**

**Syns.:** *Origanum zygis* (L.) Kuntze, *Thymus angustifolius* Salisb.

**Family:** Lamiaceae (Labiatae).

**Arabic:** Za'ater زعرور

**English name:** Spanish Thyme.

### 2. Parts used for medicinal purpose

Dried and fresh herb (3, 4).

### 3. Major chemical constituents

- **Essential oil:** the main components are thymol, carvacrol, *p*-cymene,  $\alpha$  and  $\beta$ -terpinene, linalool, terpinen-4-ol, borneol, 1,8- cineole,  $\alpha$ -thujene,  $\alpha$ -pinene, and caryophyllene (4).

- **Flavonoids:** apigenin, narigenin, kaempferol, and luteolin (and its glycosides) (5).

- **Phenolic acids:** salvianolic, rosmarinic, cinnamic, ferulic, caffeic and gallic acids (5).

- **Others:** monoterpene glycosides and diterpenes.

#### 4. Medicinal Uses (Indications)

- A. Cough associated with cold (4,10).
- B. Symptoms of bronchitis, whooping cough and catarrh of the upper respiratory tract (6-8,10).
- C. Indigestion, flatulence, dyspepsia and colic (carminative) (9).
- D. Acne (11,12).
- E. Topically for warts and inflamed swellings (13).

#### 5. Herbal preparations correlated to medicinal use

##### 1. Comminuted herbal substance as infusion

- 1.1 Comminuted herbal substance (1-2 g) in a cup of 150 ml of boiling water (4).  
One teaspoonful of the comminuted herbal substance is equivalent to 1.4 g drug (8).
- 1.2 Topical compresses: using a 5% infusion (8).

##### 2. Extracts (4):

###### 2.1 Liquid extract

- a) Extraction solvent: ammonia solution 10% (m/m), glycerol 85% (m/m), ethanol 90% (V/V), water (1:20:70:109).
- b) Extraction solvent: water (of fresh herb and often referred as expressed juice).
- c) Extraction solvent: ethanol 24% (V/V).

###### 2.2 Dry extract

- d) Extraction solvent: ethanol 70%.
- e) Extraction solvent: ethanol 96%.
- f) Extraction solvent: water.

###### 2.3 Soft extract

- g) Extraction solvent: ethanol 25% - 30% (V/V).

###### 2.4 Tincture

- h) Tincture (1:10), extraction solvent: ethanol 70% (V/V).
- i) Tincture (1:5), extraction solvent: ethanol 70% (V/V).

##### 3. Thyme oil

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

## 6. Posology and method of administration correlated to medicinal use

### General Daily Dosage (8)

The recommended daily dose is 10 g drug (with 0.03% phenols, calculated as thymol).

### Preparation 1

#### Indications A, B, C and E

- 1.1. Oral Herbal tea: 1-2 g, 3-4 times daily (4).
- 1.2. Topical: 5% infusion, 3 times daily (8).

**Method of administration:** Oral and topical use.

### Preparation 2 (4)

#### Indications A, B, C and E

##### 2.1. Liquid extract

###### - Adolescents, adults and elderly

- a) Single dose 1-4 g, 1-7 times daily, maximum daily dose 14 g.
- b) Single dose 10 ml, 3-4 times daily.
- c) Single dose: 1-2 ml, 3-4 times daily.

###### - Children between 4 and 12 years of age

- a) Single dose 0.5-0.9 ml, 3-5 times daily
- b) Single dose 7-10 ml, 2-3 times daily

##### 2.2. Dry extract

###### - Adolescents, adults and elderly

- d) Single dose 75-200 mg, 3 times daily.
- e) Single dose 135 mg, 1-3 times daily.
- f) Single dose 100 – 200 mg, 3-4 times daily.

##### 2.3. Soft extract:

###### - Adolescents, adults and elderly

- g) Single dose 50 mg, 6 times daily

#### 2.4. Tincture:

- **Adolescents, adults and elderly**

h) Single dose 40 drops, 3 times daily.

i) Single dose 2-6 ml, 3 times daily.

**Method of administration:** Oral use.

#### Preparation 3 (8,10)

##### Indication A

#### 1. Oral

**Adults and elderly:**

Single dose: 0.2-0.25 ml, 3-5 times daily

Daily dose: 0.6-1.25 ml

#### 2. Topical use

**2.1 Cutaneous use: Adults and elderly:** in liquid and semi-solid dosage forms in concentrations up to 10%; apply up to 3 times daily.

**2.2 Bath additive:**

**Adolescents, Adults and elderly:**

0.007-0.025 g per litre.

**Children 6-12 years:**

0.0035-0.017 g per litre.

**Children 3-6 years:**

0.0017-0.0082 g per litre.

One bath every day or every second day (10).

##### Indication D

**Topical use: (11-12)**

-5% Diluted oil is applied to the inflamed area.

**Method of administration:** Oral and topical use.

#### 7. Contraindications

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

- **Thyme oil** as bath additive full hot baths is contraindicated in case of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency (10).

## 8. Special warnings and precautions for use

- If the symptoms worsen or persist longer than 1 week during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- If dyspnea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted (4-10).
- **Herbal preparations (a & b):**  
The use in children under 4 years of age is not recommended without medical supervision (4).
- **Herbal preparations (c, d, e, f, g, h and i):**  
The use in children under 12 years of age has not been established (4).
- Although thyme oil has cytotoxic properties in high concentrations and may cause intestinal cell damage when administered orally, no toxicity has been reported at commonly used doses, and it can be considered as a safe drug (14).
- Like other essential oils, thyme oil should not be applied to the face particularly in the nasal area of babies and infants under the age of two years because of the risk of a laryngospasm (10).
- The use of thyme oil in children and adolescents under 18 years of age is not recommended without medical supervision (10).
- The use of thyme oil as bath additive in children under 3 years of age is not recommended without medical supervision (10).
- In cases of hypertension, a full bath should be used with caution (10).

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

None reported (4).

## 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 (4,9,15).
- Thyme oil is not recommended in pregnancy (16).
- No fertility data available (4).

## 11. Effects on ability to drive and use machines (4)

- 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.
- **Internally:** Gastric disorders may occur (4).
- The thyme oil can cause nausea and vomiting, headache, dizziness, convulsions, cardiac or respiratory arrest if taken internally (Newell et al 1996). As such, the crude herb is considered far safer (16).
- **Topically:** Thyme oil is possibly safe when applied to the skin, but in some people can cause skin irritation (7).
- Contact dermatitis reactions have been reported with topical use (16).

## 13. Overdose

No case of overdose has been reported (4).

## 14. Relevant biological activities

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





**15. Additional Information**

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**16. Date of compilation/last revision**

23/4/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

***Tilia cordata* Mill.**

تيليو

### 1. Names & Synonyms (1, 2)

***Tilia cordata* Mill.**

**Family:** Tiliaceae (Malvaceae).

**Syns:** *Tilia officinarum* Crantz, *T. officinarum* Crantz subsp. *officinarum* pro parte, *T. ulmifolia* Scop., *T. parvifolia* Ehrh. ex Hoffm.

**Arabic:** Tilio تيليو

**English:** Lime flower (3), Linden, Tilia and small leaf linden, small leaf lime (4).

***Tilia platyphyllos* Scop.**

**Family:** Tiliaceae (Malvaceae)

**Syns:** *Tilia officinarum* Crantz, *T. officinarum* Crantz subsp. *officinarum* pro parte.

**Arabic:** Tilio تيليو

**English:** Lime flower (3), Linden, Tilia and large-leaf Linden

***Tilia x vulgaris* Heyne**

Naturally-occurring hybrid of *T. cordata* and *T. platyphyllos* Scop.

**Family:** Tiliaceae (Malvaceae)

**Syn:** *T. europaea* auct. non L.

**Arabic:** Tilio تيليو

**English:** European linden, European lime tree, Linden and Tilia (4).

### 2. Parts used for medicinal purpose

Flower (2-4).

### 3. Major chemical constituents (2)

- **Flavonoids:** Kaempferol, quercetin, myricetin and their glycosides (mainly Kaempferol-3-*O*- $\beta$ -D-(6"-*E-p*-coumaroyl)-glucopyranoside "tiliroside") and proanthocyanidins (3, 5).

- **Phenolic acids:** Caffeic, chlorogenic and p-coumaric acids (3, 5).
- **Essential oil:** Alkanes (mainly tricosane) (6), phenolic alcohols and esters, and terpenes including citral, citronellal, citronellol, eugenol, limonene, nerol,  $\alpha$ -pinene and terpineol (monoterpenes), and farnesol (sesquiterpene) (3).
- **Others:** Mucilage, tocopherol (phytosterol) and amino acids (3).

#### 4. Medicinal uses (Indications)

- A. Relief cough and irritation of the throat in colds and catarrh of the respiratory tract (3, 4).
- B. Relief of mild symptoms of mental stress (3, 4).

#### 5. Herbal preparations correlated to medicinal use (3)

1. Comminuted herbal substance as herbal tea for oral use.  
1.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion
2. Liquid extract, extraction solvent ethanol 25% v/v.
3. Tincture, extraction solvent ethanol 45% v/v.
4. Aqueous extract

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

#### 6. Posology and method of administration correlated to medicinal use (3)

##### Preparation 1

##### Indication A

**Adolescents, adults and elderly:** 1.5 g as herbal tea, 2–4 times daily. Daily dose: 3-6g.  
**Children between 4 and 12 years of age:** 1 g as herbal tea, 2–4 times daily. Daily dose: 2-4 g.

##### Indication B

**Adolescents, adults and elderly:** 1.5 g as herbal tea 2–4 times daily. Daily dose: 3-6 g.

### Preparations 2 and 3

#### Indications A, B

#### Adolescents, adults and elderly

2) **Liquid extract:** 2 ml, 1-2 times daily. Daily dose: 2-4 ml.

3) **Tincture:** 1 ml, 1-2 times daily. Daily dose: 1-2 ml.

#### Preparation 4

#### Indication A

**Adolescents, adults and elderly:** extract Eq. to 3-6 gm, 2-4 times daily.

**Children between 4 and 12 years of age:** extract eq. to 2-4 gm, 2-4 times daily.

#### Duration of use:

#### Indication A

The therapy should start at first signs of common cold. If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted.

#### Indication B

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

**Method of administration:** oral use.

## 7. Contraindications (2-4)

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

## 8. Special warnings and precautions for use (3)

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- The use in children under 12 years of age is not recommended.
- In case of infusion; the use in children under 4 years of age for the relief of symptoms of common cold is not established.

## 9. Interactions with other medicinal products and other forms of interaction (2, 3)

- None reported.

## 10. Fertility, pregnancy and lactation (2, 3)

- Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
- No fertility data available.

## 11. Effects on ability to drive and use machines (3)

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

## 12. Undesirable effects (3)

- None known.
- If adverse reactions occur, a doctor or a pharmacist should be consulted.

## 13. Overdose

No case of overdose has been reported (3).

## 14. Relevant biological activities

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

## 15. Additional Information

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## 16. Date of compilation/last revision

28/06/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Urtica dioica* L.

حريق - قريص

### 1. Names & Synonyms (1)

*Urtica dioica* L.

**Family:** Urticaceae.

**Syns.:** *Urtica tibetica* W.T. Wang, *U. galeopsifolia* Wierzb. ex Opiz.

**Arabic:** hhurray حريق - Qurrays قريص

**English name:** Stinging nettle (2-4), Nettle (3, 4).

### 2. Parts used for medicinal purpose

Dried roots /rhizomes (2-5) or leaves/ herb (3-7).

### 3. Major chemical constituents

**Herb/ leaves:**

**Amines:** Acetylcholine, betaine, choline, lecithin, histamine, serotonin and a glycoprotein (8).

**Flavonoids:** Flavonol glycosides (e.g. isorhamnetin, kaempferol, quercetin), isoquercitrin, astragalinalin and rutin (7-9).

**Inorganics:** Up to 20% minerals, including calcium, potassium and silicon (8,9).

**Lignans:** Several lignans, including (-)-secoisolariciresinol (8).

**Other constituents:** Choline acetyltransferase, scopoletin,  $\beta$  sitosterol and tannin (8).

**Rhizomes (8):**

Lectin (agglutinin) composed of six isolectins, Coumarin (scopoletin).

**Triterpenes:**  $\beta$ -sitosterol its glucoside, and six stearyl derivatives; two phenylpropane derivatives and six lignans.

**Roots (10-12):**

**Polysaccharides:** Glycans, glucogalacturonans, arabinogalactan acid, fatty acid: (10E, 12Z)-9-hydroxy-10, 12-octadecadienoic acid, lectins, ceramides, terpenes diols, and terpenes diols glucosides.



#### 4. Medicinal Uses (Indications)

- A. Relief of lower urinary tract symptoms related to benign prostatic hyperplasia after serious conditions have been excluded by a medical doctor (2-5).
- B. As a diuretic (2-4, 6, 7). To increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints (6), as irrigation therapy for inflammatory diseases of the lower urinary tract and for prevention and treatment of kidney stones (12).
- C. Relief of minor articular pain. Supportive therapy to help relieve rheumatic complaints (2-4, 7) and for the symptomatic treatment of arthritis and rheumatic conditions (6,7).

#### 5. Herbal preparations correlated to medicinal use

1. Comminuted herbal substance as herbal tea for oral use as a decoction or an infusion (5, 6):
  - i. 1.5 g of the root as a decoction (5).
  - ii. 2-4 g of the comminuted herb or leaves as an infusion (6).
2. Dry root extract, extraction solvent ethanol 20% V/V (5).
3. Dry root extract, extraction solvent ethanol 70% V/V (5).
4. Liquid root extract, extraction solvent ethanol 30% V/V (5).
5. Liquid leaves extract, extraction solvent ethanol 96% (V/V) (6).
6. Dry leaves extract (4.7-6:1), extraction solvent water (6).
7. Dry leaves extract (5-10:1), extraction solvent water (6).
8. Dry leaves extract, extraction solvent ethanol 50% (V/V) (6).
9. Leaves tincture 1:5 (25% (7)- 45% (8) ethanol).

**Herbal preparations (2-9) are in a pharmaceutical dosage form. The pharmaceutical form should be described by the pharmacopoeia full standard term.**

## 6. Posology and method of administration correlated to medicinal use

### Indication A

#### Adults and elderly (5)

1. (i) 1.5 g as herbal tea 3-4 times daily.
2. 240 mg, 3 times daily.
3. 150-190 mg, twice a day.
4. Maximum 5 ml daily, divided into 3 or 4 single doses.

**There is no relevant use in children and adolescents under 18 years of age.**

#### Duration of use

Long-term use, no longer than 6 months (5,13), is possible.

**Method of administration:** oral use (5).

### Indications B, C (6)

#### Adults and elderly

1. (ii) 2-4 g as herbal tea 3-6 times daily (the daily dose 8-12 g) (8,12).
5. 30-40 oral drops as a single dose, 3-4 times daily.
6. 750 mg as a single dose, 2-3 times daily.
7. 450 mg as a single dose, 3 times daily.
8. 540 mg as a single dose, 2 times daily.
9. 2-6 ml, 3 times daily (7,8).

#### Duration of use (6)

### Indication B

Not to be used for more than 2- 4 weeks.

### Indication C

Not to be used for more than 4 weeks.

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

**Method of administration:** oral use (6).

## 7. Contraindications

- Hypersensitivity to the active substances and to other plants of the same family (5,6).
- Nettle leaves are contraindicated in condition where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease) (6).

## 8. Special warnings and precautions for use

- If complaints worsen or if symptoms such as fever, spasms or blood in the urine, painful urination, or urinary retention occur during the use of the medicinal product, a doctor or a pharmacist should be consulted (2,5,6).
- When articular pain is accompanied by swelling of joint, redness or fever a doctor should be consulted (6).
- Use of nettle leaves in children under the age of 12 years is not recommended (6).

## 9. Interactions with other medicinal products and other forms of interaction (4)

- **Anticoagulants (heparin, warfarin) and anticoagulant herbs:** Nettle may decrease the effect of anticoagulants.
- **CNS depressants (alcohol, barbiturates, sedative/hypnotics , antipsychotics, opiates) and sedative herbs:** Nettle may lead to increased central nervous system depression.
- **Diuretics:** Use of nettle may increase the effects of diuretics, resulting in dehydration and hypokalemia.
- **Iron salts:** Nettle tea may interfere with the absorption of iron salts.
- **Lithium:** Nettle combined with lithium may result in dehydration, lithium toxicity .

## 10. Fertility, pregnancy and lactation

- The use during pregnancy and lactation is contraindicated (2-4) owing to its effects on androgen and estrogen metabolism (2).

## 11. Effects on ability to drive and use machines (5,6)

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.
- Gastro-intestinal complaints such as nausea, heartburn, feeling of fullness, flatulence, diarrhoea may occur (2, 4, 5-8).
- Allergic reactions *i.e.*, pruritus, rash, urticaria may occur (2,4, 5-7).

## 13. Overdose (5,6)

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

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## 16. Date of compilation/last revision

25/6/2022

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# Egyptian Herbal Monograph

## Medicinal Plants Used in Egypt

*Zingiber officinale* Roscoe

چنزبیل

### 1. Names & Synonyms (1)

*Zingiber officinale* Roscoe.

**Family:** Zingiberaceae.

**Syns.** *Amomum zingiber* L., *Zingiber blancoi* Massk.

**Arabic:** Janzabeil چنزبیل - Zanzabeel زنجبیل - Zingibil زنجبیل

**English:** Ginger.

### 2. Parts used for medicinal purpose

The dried rhizome (1-4).

### 3. Major chemical constituents (4, 5)

- **Oleo-resin:** Gingerols, shogaols, paradols, zingerone, gingerenone-A, and 6-dehydrogingerdione.
- **Essential oil:**  $\beta$ -Bisabolene and zingiberene, zingiberol, zingiberenol, *ar*-curcumene,  $\beta$ -sesquiphellandrene,  $\beta$ -sesquiphellandrol (*cis* and *trans*), phellandrene, camphene, geraniol, neral, linalool, *d*-nerol).
- **Others:** Starch, lipids, proteins and amino acids.

### 4. Medicinal uses (Indications)

- A. Prevention of nausea and vomiting in motion sickness (1-3, 6), postoperative nausea and seasickness (1).
- B. Symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence (1-4), lack of appetite, indigestion, dyspepsia (1, 3, 4, 6).
- C. Expectorant (3, 6) and cough suppressant (antitussive), to help relieve bronchitis (3) as well as colds (1, 3, 6).
- D. Adjunctive treatment for inflammatory conditions, such as osteoarthritis and rheumatoid arthritis (1, 4, 7).

## 5. Herbal preparations correlated to medicinal use

1. Comminuted herbal substance as herbal tea for oral use as decoction.  
1.5 teaspoonful of the comminuted herbal substance in 1 cup of boiling water (7).
2. Powdered herbal substance (1-3).
3. Ethanolic extracts (dry extract, fluid extract, tincture) (3, 7).
4. Aqueous dry extracts (3, 7).

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

## 6. Posology and method of administration correlated to medicinal use

### Indication A

#### Preparation 1

- **Adults:** 0.7-3g as infusion (3) or decoction (3, 7).
- **Adolescents and children more than 6 years:** 0.7-3g as infusion or decoction (3).

Take a single dose 30 minutes before travel or every 4 hours as needed (optional) (3).

#### Preparation 2

- **Adults:** 1-2 g, 30 minutes to one hour before traveling or upon arising (2, 4, 7) or 0.5 g, 2-4 times daily as needed (1, 4) without exceeding the maximum daily dose of 3g (3).
- **Adolescents:** 750 mg, 30 minutes before travelling (2) or 0.5 g, 2-4 times daily as needed (1) without exceeding the maximum daily dose of 3g (3).
- **Children between 6 and 12 years of age:** 250 or 500 mg, 30 minutes before travelling (2) or 0.5 g, 2-4 times daily as needed (1) without exceeding the maximum daily dose of 3g (3).

#### Preparation 3

- **Adults:** 100-200 mg extract, standardized to 20% gingerol and shogaol (7) or extracts equivalent to 0.5g, 2-4 times daily (1) without exceeding the maximum daily dose of 3g of dried rhizome equivalent (3).
- **Adolescents and children more than 6 years:** extracts equivalent to 0.5g, 2-4 times daily (1) without exceeding the maximum daily dose of 3g of dried rhizome equivalent (3).

#### Preparation 4

- **Adults:** 100-200 mg extract, standardized to 20% gingerol and shogaol (7) or extracts equivalent to 0.5 g, 2–4 times daily (1) without exceeding the maximum daily dose of 3g of dried rhizome equivalent (3).
- **Adolescents and children more than 6 years:** extracts equivalent to 0.5-0.7 g, 2–4 times daily (1, 3) with maximum daily dose of 3g of dried rhizome equivalent (3).

#### Indication B

##### Preparation 1

**Adults, adolescents and Children more than 6 years:** 0.7-3 g as infusion or decoction (3).

##### Preparation 2

- **Adults:** 180 mg, 3 times daily (2) or 0.5 g, 2-4 times daily (1) without exceeding the maximum daily dose of 3g of dried rhizome (3).
- **Adolescents and children more than 6 years:** 0.3–3g of dried rhizome daily (3).

##### Preparation 3

- **Adults:** extracts equivalent to 0.3-0.5 g, 2–4 times daily (1, 3) without exceeding the maximum daily dose of 3g of dried rhizome equivalent (3).
- **Adolescents and children more than 6 years:** extracts equivalent to 0.3- 3g of dried rhizome, daily (3).

##### Preparation 4

- **Adults:** extracts equivalent to 0.5-0.7g, 2–4 times, daily (1, 3) without exceeding the maximum daily dose of 3g of dried rhizome equivalent (3).
- **Adolescents and children more than 6 years:** extracts equivalent to 0.7- 3g of dried rhizome, daily (3).

#### Indication C (3)

**Adults, adolescents, and children more than 6 years:**

**Preparation 1:** 0.7g-3g of dried rhizome as infusion or decoction.

**Preparation 2:** powdered herbal substances equivalent to 0.3–3 g of dried rhizome daily.

**Preparation 3:** ethanolic extract equivalent to 0.3- 3 g of dried rhizome daily.



**Preparation 4:** aqueous extract equivalent to 0.7- 3 g of dried rhizome daily.

**Indication D (7)**

**Preparation 3, 4**

**Adults:** 100-200 mg extract, standardized to 20% gingerol and shogaol.

**Duration of use (2)**

If the symptoms persist longer than 5 days (for indication A) or longer than 2 weeks (for indication B) during the use of the medicinal product, a doctor or a pharmacist should be consulted.

**Method of administration:** oral use (2).

## 7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Ginger should not be used by persons with cholelithiasis (6, 7).
- It should not be used during childhood fevers or in children with gallstones (7).

## 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.
- The use in children and adolescents under 6 years of age is not recommended (1-3).

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

Ginger may increase plasma partial prothrombin time in clients taking warfarin concurrently and may increase prothrombin time (6, 7).

## 10. Fertility, pregnancy and lactation

- Ginger use in pregnancy is avoided (2). Ginger is reputed to be an abortifacient and utero-activity has been documented for a related species (4).
- Safety during lactation has not been established. In the absence of sufficient data, the use during lactation is not recommended.
- No fertility data available.

### **11. Effects on ability to drive and use machines (2)**

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.
- Minor gastrointestinal complaints, particularly stomach upset, eructation, dyspepsia and nausea have been reported (2).

### **13. Overdose**

No case of overdose has been reported (2).

### **14. Relevant biological activities**

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

### **15. Additional Information**

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### **16. Date of compilation/last revision**

28/06/2022

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