# **Egyptian Herbal Monograph**

# Volume 3 Herbal Formulations used in Egypt

Egyptian Drug Authority (EDA)
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# **Egyptian Herbal Monograph Herbal Formulations Used in Egypt**

Thyme/ Primula

زعتر/ زهرة الربيع

# 1. Names & Synonyms

#### **Thyme**

## Thymus vulgaris L. (1)

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

Family: Lamiaceae (Labiatae).

Arabic: Za'ater زعتر.

English name: English Thyme, Garden Thyme.

#### Thymus zygis L. (2)

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

Family: Lamiaceae (Labiatae).

Arabic: Za'ater زعتر.

**English name:** Spanish Thyme.

#### Primula (3)

#### Primula veris L.

Family: Primulaceae.

**Syns.:** *Primula officinalis* (L.) Hill.

زهرة الربيع Zahrat El-rabee' , زهر الحقل Arabic: Zahr El-hakl

English name: Cowslip, Primula (2-4).

# 2. Parts used for medicinal purpose

**Thyme:** Dried and fresh herb (1, 2, 5).

Primula: Root (6-11).

# 3. Major chemical constituents

#### Thyme:

- **Essential oil:** 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) (12).



- Phenolic acids: Salvianolic, rosmarinic, cinnamic, ferulic, caffeic and gallic acids (12).
- **Others**: Monoterpene glycosides (13).

#### Primula:

- **Triterpene saponins**: Primula saponins I and II, priverosaponin B22-acetate (6, 14, 15).
- **Phenolic glycosides**: Primverin and Primulaverin (6, 14).

# 4. Medicinal uses (Indications)

- **A.** Expectorant in case of productive cough (16).
- **B.** Treat symptoms of acute bronchitis and respiratory infections with thick phlegm following exposure to cold (17).

## 2. Herbal preparations correlated to medicinal use (16)

- **1.** Thyme liquid extract (Extraction solvent: Ammonia solution 10%, glycerol 85%, ethanol 90%, water (1:20:70:109)) and Primula liquid extract (Extraction solvent: Ethanol 70%).
- **2.** Thyme liquid extract (Extraction solvent: Ammonia solution 10%, glycerol 85%, ethanol 90%, water (1:20:70:109)) and Primula liquid extract (Extraction solvent: Ethanol 55%).
- **3.** Thyme liquid extract (Extraction solvent: Ammonia solution 10%, glycerol 85%, ethanol 90%, water (1:20:70:109)) and Primula tincture (1:5) (Extraction solvent: Ethanol 50%).
- **4.** Thyme liquid extract (Extraction solvent: Ammonia solution 10%, glycerol 85%, ethanol 90%, water) (1:20:70:109)) and Primula soft extract (Extraction solvent: Ethanol 55%).
- **5.** Thyme liquid extract (Extraction solvent: Ethanol 20%) and Primula liquid extract (Extraction solvent: Ethanol 15%).
- **6.** Liquid extract from mixture of Thyme and Primula (Extraction solvent: Water).
- **7.** Dry extract from Thyme (Extraction solvent: Ethanol 70%) and dry extract from Primula, (Extraction solvent: Ethanol 47.4%).
- **8.** Dry extract from Thyme (Extraction solvent: Ethanol 70%) and dry extract from Primula (Extraction solvent: Water).

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



# 3. Posology and method of administration correlated to medicinal use (16)

# Preparation 1

#### **Indication A**

**Adolescents, adults and elderly:** Single dose: 500 mg Thyme extract and 250 mg Primula extract, 6 times daily.

**Children 4-11 years:** Single dose: 330 mg Thyme extract and 170 mg Primula extract, 3-5 times daily.

#### **Indication B**

**Infants 6-12 months:** 65 mg Thyme extract and 32.4 mg Primula extract, 6 times daily. Total daily dose: 390 mg Thyme extract and 194.4 mg Primula extract.

**Children 1-4 years:** 162.5 mg Thyme extract and 81 mg Primula extract, 6 times daily. Total daily dose: 975 mg Thyme extract and 486 mg Primula extract.

**Children above 5 years, adolescents and adults:** 487.5 mg Thyme extract and 243 mg Primula extract, 4 times daily. Total daily dose: 1950 mg Thyme extract and 972 mg Primula extract.

## **Preparation 2**

#### **Indication B**

**Adults:** 500 mg Thyme extract and 250 mg Primula extract, 3 times daily.

**Children above 4 years**: 250 mg Thyme extract and 125 mg Primula extract, 3 times daily.

#### **Preparation 3**

#### **Indication A**

**Adolescents, adults and elderly**: 430 mg Thyme extract and 210 mg Primula tincture, 5 times daily.

**Children 4-11 years:** 360 mg Thyme extract and 180 mg Primula extract, 3-5 times daily.

#### **Preparation 4**

#### **Indication A**

**Adolescents, adults and elderly:** 1160 mg Thyme extract and 170 mg Primula extract, 4 times daily.

**Children 4 -11 years:** 770 mg Thyme extract and 120 mg Primula extract, 3-4 times daily.

#### **Preparation 5**

#### **Indication A**

**Adolescents, adults and elderly:** 1240 mg Thyme and 410 mg Primula, 3-5 times daily.

# **Preparation 6**



#### Indication A

**Adolescents, adults and elderly:** 3080 mg equivalent to: 620 mg Thyme extract and 220–510 mg of Primula extract, 4 times daily.

Preparation 7
Indication A

**Adults and elderly:** 160 mg Thyme extract and 60 mg Primula extract, 3 times daily.

**Preparation 8** 

**Indication A** 

**Adolescents, adults and elderly:** 75 mg dry Thyme extract and 37.5 mg dry Primula extract, 3 times daily.

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

Method of administration: Oral use.

#### 4. Contraindications

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

# 5. Special warnings and precautions for use

- If the symptoms worsen or persist longer than one 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 (4-6, 16).
- The use in children under 4 years (Herbal preparations 2, 3 and 4), under 12 years (Herbal preparations 5, 6 and 8) and under 18 years (Herbal preparation 7) is not recommended without medical supervision (5, 16).
- Insufficient data are available concerning administration in infants under 6 months (Herbal preparation 1). Therefore, it should not be given to infants under 6 months.
- Caution is recommended in patients with gastritis or gastric ulcer (16).

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

None reported (16).

# 7. Fertility, pregnancy, and lactation (16)

- 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.

# 8. Effects on ability to drive and use machines (16)

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

## 9. Undesirable effects

- If adverse reactions occur, a doctor or a pharmacist should be consulted.
- Gastric disorders, nausea and allergic reactions may occur (6, 16).

### 10.Overdose

No case of overdose has been reported (16).

# 11. Relevant biological properties

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

# 12. Additional information

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# 13. Date of compilation/last revision

06/08/2023.

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