

Egyptian Herbal Monograph

Volume 2

Medicinal Plants used in Egypt

Egyptian Drug Authority (EDA)

2025



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Primula veris L.

زَهْرَةُ الرَّبِيعِ

1. Names & Synonyms (1)

Primula veris L.

Family: Primulaceae

Syns.: *Primula officinalis* L. Hill.

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

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

2. Parts used for medicinal purpose

Dried Flowers and Roots (2-4).

3. Major chemical constituents

Flowers:

- Phenolic compounds: including flavonoids as rutin and isorhamnetin 3-O-rutinoside (5), hyperoside catechin, astragalin and catechin (6).

Leaves:

- Kaempferol 3-O-rutinoside-7-O-rhamnoside, rutin, vitamin C (5).

Roots:

- Triterpene saponins (6): Primula saponins I and II, priverosaponin B22-acetate (4, 5).
- Phenolic glycosides: primverin and primulaverin (4, 6).

4. Medicinal Uses (Indications)

Expectorant in cough associated with cold (4).

5. Herbal preparations correlated to medicinal use (4)

1. Comminuted herbal substance as herbal tea for oral use

1.1 Roots.

1.2 Flowers.

2. Dry extract (DER 3-9:1), extraction solvent ethanol 40-50 % v/v (Roots).

3. Liquid extract

3.1 Extraction solvent ethanol, 70 % v/v (Roots), (DER 1:1).

3.2 Extraction solvent ethanol 70% v/v (Roots), (DER 1:2.0-2.5).

3.3 Extraction solvent ethanol 25% v/v (flowers), (DER 1:1).

4. Tincture (1:5), extraction solvent ethanol 70 % v/v (Roots).

5. Soft extract (Roots)

1.1 Extraction solvent water (DER 5-10:1).

5.2 Extraction solvent ethanol 20-55% v/v, (DER 1-4:1).

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

6. Posology and method of administration correlated to medicinal use (4)

Preparation 1

Preparations 1.1

Adolescents, adults, elderly: 0.2 – 0.5 g in 150 ml of boiling water as an herbal infusion, 3 times daily.

Preparation 1.2

Adolescents, adults, elderly: 1 g in 150 ml of boiling water as an herbal infusion, 3 times daily.

Preparation 2

Adolescents, adults, elderly:

- Single dose: 0.1 – 0.2 g, 3 times daily.
- Single dose equivalent to 0.2 – 0.5 g herbal substance, 3 times daily.

Preparation 3

Preparations 3.1

Adolescents, adults, elderly: Single dose: 0.5 g, 3 times daily.

Preparations 3.2

Adolescents, adults, elderly: Single dose: 0.6 g, 4 times daily.

Children between 4-12 years of age: Single dose 0.33 g, 3 times daily.

Preparations 3.3

Single dose: 1 - 3 ml, up to 3 times daily, Maximum daily dose 6 ml (2, 3).



Preparation 4

Adolescents, adults, elderly: Single dose: 0.5 – 1 g, 3 times daily.

Children between 4-12 years of age: Single dose 0.3 – 0.5 ml, 3 times daily.

Preparation 5

Preparations 5.1 and 5.2

Adolescents, adults, elderly: Single dose equivalent to 0.2 – 0.5 g herbal substance, 3 times daily.

Preparation 5.2

Children between 6 - 12 years of age: Single dose 0.12 g, 3-4 times daily.

Children between 4 - 6 years of age: Single dose 0.12 g, 3 times daily.

Duration of use

If the symptoms persist longer than 1 week, a doctor or a pharmacist should be consulted.

Method of administration: Oral use.

7. Contraindications

Hypersensitivity to the active substance or to other Primula species (4).

8. Special warnings and precautions for use (4)

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- Preparations **1, 2, 3.1, 3.3 and 5.2**: The use in children under 12 years of age is not recommended.
- Preparations **3.2, 4 and 5.2**: The use in children under 4 years of age is not recommended.
- Caution is recommended in patients with gastritis or gastric ulcer.
- If dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.

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

- **Antihypertensives, diuretics:** Cowslip may increase the effect of antihypertensives, diuretics.
- **CNS depressants:** Cowslip may increase the effect of antianxiety agents and sedatives/hypnotics; concurrent use should be avoided.

- **Lab Test: AST, ALT, alkaline phosphatase:** Cowslip may increase these levels.

10. Fertility, pregnancy and lactation (4)

- 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 (4)

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

13. Overdose (4)

Overdose may lead to stomach upset, vomiting or diarrhoea.

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 last revision

06/09/2022.

References

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5	Tarapatsky, M., Gumienna, A., Sowa, P., Kapusta, I. and Puchalski, C. (2021). Bioactive phenolic compounds from <i>Primula veris</i> L.: Influence of the extraction conditions and purification. <i>Molecules</i> , 26 (4), 997.
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