Egyptian Herbal Monograph

Volume 2 Medicinal plants used in Egypt

Egyptian Drug Authority (EDA)
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Egyptian Herbal Monograph Medicinal Plants Used in Egypt

Capsicum annuum L. and Capsicum frutescens L.

الشطة

1. Names & Synonyms (1)

Capsicum annuum L.

Syns.: Capsicum indicum var. vulgatum <u>Dierb.</u>

Capsicum frutescens L.

 $\textbf{Syns.: } \textit{Capsicum annuum} \underline{\text{var. }} \textit{frutescens} \underline{\text{(L.) Alef.}}, \textit{Capsicum indicum} \underline{\text{Dierb.}}, \textit{Capsicum}$

indicum var. berberideum Dierb.-

Family: Solanaceae.

Arabic name: Al shatta الشطة

English name: Capsicum, Cayenne, Chilli Pepper, Hot Pepper, Paprika, Red Pepper and Tabasco

Pepper (2-8).

2. Parts used for medicinal purpose

- Dried fruits (5-7).

3. Major chemical constituents

- **Capsaicinoids:** Capsaicin, dihydrocapsaicin (9).
- **Carotinoids:** Capsanthin and mixed carotenoids, as β -carotene, β -cryptoxanthin, zeaxanthin, capsorubin, lutein, violaxanthin, antheraxanthin (10).
- **Vitamins**: Vitamin B complex, ascorbic acid (vitamin C), vitamin A (11).
- **Minerals:** Zinc, iron, calcium, potassium, sodium, sulfur (11).
- **Others**: Volatile oils (12), protein, carbohydrates, dietary fibers (13).

4. Medicinal Uses (Indications)

- **A.** Relief of muscle pain such as low back pain and muscular tension (2,7,8).
- **B.** Temporary relief (counterirritant) of muscle and joint pain associated with rheumatoid arthritis or osteoarthritis, and pain of tendons and ligaments (3,5,8).
- **C.** Relief cutaneous pain associated with conditions such as post-herpetic neuralgia and/or diabetic neuropathy (3,5).
- **D.** Used for colic, flatulent dyspepsia without inflammation, aid digestion and insufficiency of peripheral circulation (4,5).



5. Herbal preparations correlated to medicinal use

- **1.** Powdered drug (4,5).
- 2. Soft extracts (2)
 - **2.1** Extraction solvent: ethanol 80%, standardized to 2.0–2.78% total capsaicinoids.
 - **2.2** Extraction solvent: ethanol 96%.
 - **2.3** Extraction solvent: propan-2-ol.
- **3.** Dry extract (3).
- **4.** Fluid extract (3).
- **5.** Tincture

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5.1 1: 5 (6). 5.2 1:10 (3,5,8).
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6. Oleoresin (5).

Herbal preparations 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

Preparation 1

Indication D

Adults: For oral use

- 30 120 mg, 3 times daily (5).
- 15 650 mg, daily (4).

Preparation 2

Indication A

Adults and elderly: For cutaneous use/topical:

Preparation 2.1

- One medicated plaster (22 x 14 cm) containing soft extract, corresponding to 11 mg capsaicinoids expressed as capsaicin (= $35 \mu g / cm^2$).
- One medicated plaster (12 x 18 cm) corresponding to 4.8 mg capsaicinoids expressed as capsaicin (= $22 \,\mu g / cm^2$).

Daily dose: A maximum of one plaster per day should be applied on the affected area for at least 4 and up to 12 hours. There should be an interval of at least 12 hours before a new plaster is applied at the same application area.

Preparations 2.1, 2.2 and 2.3

Semi-solid dosage forms corresponding to 40-53 mg capsaicinoids / 100 g. To be applied in a thin layer on the affected area, 2-4 times daily.



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Preparations 3, 4 and 5 (3)

Indication B

Adults and elderly: For cutaneous use/ topical, equivalent to 0.01-0.05% or 0.025-0.075% capsaicin

Indication C

Adults and elderly: For cutaneous use/topical, equivalent to 0.075% capsaicin.

Direction for use (3)

Apply thinly and evenly to affected area up to 3-4 times per day. Rub and/or massage into skin until solution vanishes.

Duration of Use

Use for at least 1-4 weeks to see beneficial effects.

Preparation 5

Adults

Preparation 5.1

Indication D

- For oral use: 5 - 15 drops in water, 4 times daily (6).

Preparation 5.2

Indications B and C

- For cutaneous use: Apply a few drops to the affected area of the skin and rub in thoroughly, several times daily (8).

Indication D

- For oral use: 0.3 – 1.0 ml, capsaicin content 0.005–0.01% (5).

Preparation 6

Adults:

Indications B and C

- For cutaneous use: 2.5% maximum strength (5).

Indication D

- For oral use: 1.2 - 1.8mg, daily in divided doses (5).

Duration of use (2-4)

- The medication should be continued until relief of pain is achieved, if necessary up to 3 weeks. After 3 weeks of use a break of, at least 2 weeks, is required.
- Use topically for at least 1 4 weeks to see beneficial effects.

Method of administration:

- Cutaneous use (for indications A-C) (1,2,8): Hands should be washed with soap and water after touching or handling the plaster/semisolid dosage form.
- Oral use (for indication D) (4).



7. Contraindications

- Hypersensitivity to the active substance or to other sources of capsaicinoids (e.g. pepper plants).
 - Broken skin, wounds and eczema (2).

8. Special warnings and precautions for use (2,3)

- 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.
- The medicinal product should not be applied near the eyes or to mucous membranes.
- It is recommended not to scratch the application site to avoid damage to the skin.
- Application of additional sources of heat during treatment should be avoided (e.g. solar or infrared radiation, heating pad or warm water).
- The effect of warmth can also be intensified by physical activity (sweating).
- Treatment should be discontinued if the heat effect is experienced as excessive. In this case the plaster or the surplus of the semi-solid dosage form should be removed.
- Do not tightly bandage.
- Stop use if headache, erythema, redness, rashes, burning discomfort or hypersensitivity occur.

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

- The plaster/semisolid dosage form is not intended to be applied at the same time as other topical products e.g. other rubefacients (which increase the perfusion and cause a reddening of the skin) or pain-relieving gels at the same application site (2).
- Interactions with other products applied at the same application site may even occur up to 12 hours after the plaster has been removed (2).

10. Fertility, pregnancy and lactation (2,5)

- 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 (2)

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



12. Undesirable effects

Medicated plaster

The active ingredient causes increased local blood circulation with marked reddening of the skin and a sensation of warmth. This reaction is part of the normal pharmacological action of the preparation and subsides as a rule within a short time after removal of the plaster (2).

- Semi-solid dosage forms

The active ingredient causes increased local blood circulation with marked reddening of the skin and a sensation of warmth. This reaction is part of the normal pharmacological action of the herbal preparation. Skin hypersensitivity and allergic reactions (e.g. urticaria, blisters or vesiculation at the application site) may occur. The treatment is to be stopped in such cases immediately. If, in individual cases, burning sensation or stinging or itching are experienced as excessive, treatment should be discontinued (2).

- Capsicum may cause gastrointestinal irritation if taken orally (5).

13. Overdose

- No case of overdose has been reported when applied externally (2).

14. Relevant biological activities

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

15. Additional information (3)

- For topical/cutaneous application, the following dosage forms are acceptable when used according to the requirements indicated: Cream; Gel; Liniment; Lotion; Oil; Ointment; Tincture and Topical liquid.
- For standardized Cayenne fruit powder or extract, the percentage of capsaicin should also be included on the product label.

16. Date of last compilation/last revision

04/12/2023



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