

Egyptian Herbal Monograph

Volume 3

Medicinal Plants used in Egypt

Egyptian Drug Authority (EDA)

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***Nigella sativa* L.**

حبة البركة - الحبة السوداء

1. Names & Synonyms (1, 2)

***Nigella sativa* L.**

Family: Ranunculaceae

Syns: *Nigella cretica* Mill., *Nigella indica* Roxb. ex Flem., *Nigella truncata* Viv.

Arabic: al-haba-el-sauda حبة البركة, habat-al-baraka الحبة السوداء

English: Nigella, black seed, black cumin, black caraway.

2. Parts used for medicinal purpose (3, 4)

Dried mature seeds.

3. Major chemical constituents (5-7)

-Fixed oil: Unsaturated fatty acids (linoleic, oleic, eicosadienoic and dihomogamma-linolenic acid(DGLA)) and saturated fatty acids (palmitic and stearic acids).

-Essential oil: Thymoquinone, thymohydroquinone, dithymoquinone (nigellone), *p*-cymene, carvacrol, 4-terpineol, *t*-anethole, sesquiterpene longifolene, α -pinene and thymol.

-Alkaloids: Isoquinoline alkaloids (e.g. nigellicimine and nigellicimine-N-oxide) and pyrazole alkaloids (e.g.: nigellidine and nigellicine).

-Others: Sterols (β -sitosterol, stigmasterol), protein, carbohydrates, vitamins and minerals.

4. Medicinal uses (Indications) (3,8-10)

A. Relief symptoms of asthma.

B. Amelioration of Hyperlipidemia (Dyslipidemia).

C. As adjuvant therapy for managing hypertension.

D. As adjuvant therapy for controlling of blood glucose levels in Type 2 diabetes mellitus.

E. Modulate immune system.

F. As adjuvant therapy to improve inflammatory conditions (Anti-inflammatory)

(11-15).

5. Herbal preparations correlated to medicinal use (3,8,10)

1. Powdered seeds.
2. Aqueous extract.
3. Oil.

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 A

500 mg - 1.0 g twice daily, for 3 months (16).

Indication B

- 1.0 g daily, for 1-2 months (9).
- 500 mg daily, for 6 months (9), up to 1.0 g, twice daily (2.0 g daily), for 3 months (3, 17).

Indication C

200 - 400 mg daily, for 2 months (9).

Indication D

2.0 – 3.0 g daily, for 3 months (3, 9,17).

Indication F

2 g daily, for 3 months (11).

Method of administration: Oral use.

Preparation 2

Indication A

- 2.0 g extract daily, for 2 weeks (21).
- 700 mg – 1.4 g extract daily, as adjuvant therapy (22).

Indication C

100–200 mg twice daily, for 2 months (3, 17, 10).

Method of administration: Oral use.

Preparation 3

Indication A

- 5 ml 3 times daily (3).
- 500 mg twice daily, for 4 weeks (23).

Indication B

5 ml or 2.0 –3.0 g daily, for 2- 3 months (3, 9).

Indication C

- 5 ml daily, for 2-3 months (3, 9).
- 2.5 ml twice daily, for 2 months (9).

Indication D

5 ml once or 2.5 ml twice daily, for 6 weeks (3, 9,10) up to 3 months (9).

Indication E

500 mg daily (18).

Method of administration: Oral use.

Indication F

- **Orally:** 500 mg, twice daily, for 1-2 months (12,13), up to one g, twice daily, for 3 months (14).
- **Topical application:** twice daily (in the morning and night) for 21 days (15) or 600mg twice daily for 2months (9).

Method of administration: Oral and topical 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 (3,19,20)

- **Anti-diabetic drugs:** might decrease blood sugar levels. Blood sugar should be monitored closely (24).
- **Antihypertensive drugs:** might decrease blood pressure levels. Blood pressure should be monitored closely.

- **Immunosuppressants:** concurrent use might decrease the effects of these medications.
- **Anticoagulant / antiplatelet drugs:** might increase the risk of bruising and bleeding.
- **CNS depressants:** might cause breathing problems and/or too much sleepiness.
- **Diuretic drugs:** might make potassium levels drop too low.
- **Serotonergic Drugs:** might increase serotonin too much. This might cause serious side effects including heart problems, seizures and vomiting.

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 (25).
- The oil is contraindicated in pregnancy and breastfeeding (24).
- No enough data available about fertility.

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 (19,20)

- If other adverse reactions occur, a doctor or a pharmacist should be consulted.
- Black seed can cause allergic rashes in some people. It can also cause stomach upset, vomiting, or constipation.

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

19 /7/2022.

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