



Egyptian Herbal Monograph

Volume 3

Medicinal plants used in Egypt

Egyptian Drug Authority (EDA)

2022



*Citation: Egyptian Herbal Monograph(2022). Nigella sativa, 325-330.
EDA, Egypt*

Egyptian Herbal Monograph

Medicinal Plants Used in Egypt

***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 الحبة السوداء, habat-al-baraka حبة البركة

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).



هَيْبَةُ الرَّوَّاحِ الْمَضْرُوبَةِ

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).



هبة الازواج الصبرية

- **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

-

16. Date of compilation/last revision

19/7/2022



هَيْئَةُ الدَّوَاءِ الْمَصْرِئِيَّة

References

1	https://powo.science.kew.org/taxon/urn:lsid:ipni.org:names:711687-1 .
2	Herbal Medicine Compendium (2021). https://hmc.usp.org/monographs/nigella-sativa-seed-0-1 .
3	Ahmed, M., editor (2017). Monographs on Research oriented Natural Drugs in Modern Medical Systems. Pakistan Society of Pharmacognosy, University of Karachi. http://www.pspuok.com/books/monograph%20on/33.pdf
4	Isa, T., Ayse, S-Y., Ferda, E., Huseyin, A., Ibrahim, D. and Saban, T. (2014). Comparison of seed oil composition of <i>Nigella sativa</i> L. and <i>N. damascene</i> L. during seed maturation stages. <i>Journal of the American Oil Chemists' Society</i> , 91 (10), 1723-1729. doi:10.1007/s11746-014-2513-3.
5	Forouzanfar, F., Bazzaz, B. S. and Hosseinzadeh, H. (2014). Black cumin (<i>Nigella sativa</i>) and its constituent (thymoquinone): A review on antimicrobial effects. <i>Iran J. Basic Med. Sci.</i> , 17 (12): 929-38.
6	Majid, A. (2018). The chemical constituents and pharmacological effects of <i>Nigella sativa</i> - A Review. <i>Journal of Bioscience and Applied Research</i> , 4 (4), 389-400.
7	Srinivasan, K. (2018). Cumin (<i>Cuminum cyminum</i>) and black cumin (<i>Nigella sativa</i>) seeds: traditional uses, chemical constituents, and nutraceutical effects. <i>Food Quality and Safety</i> , 2 (1), 1-16, https://doi.org/10.1093/fqsafe/fyx031
8	Malhotra, S. K. (2004, 2012). <i>Nigella: Handbook of Herbs and Spices</i> , 2 nd ed., Volume 2, 219-242, 391-416. Woodhead Publishing. https://search.yahoo.com/search?fr=mcafee&type=E211US105G91649&p=Nigella+S.+K.+M.alhotra https://www.researchgate.net/publication/323691873_13_Nigella
9	Tavakkoli, A., Mahdian, V., Razavi, B. M. and Hosseinzadeh, H. (2017). Review on clinical trials of black seed (<i>Nigella sativa</i>) and its active constituent, thymoquinone. <i>Journal of Pharmacopuncture</i> , 20 (3): 179-193.
10	Salehi, B., Quispe, C., Imran, M., Ul-Haq, I., Zivkovi, J., Abu-Reidah, I. M., Sen, S., Taheri, Y., Acharya, K., Azadi, H., Contreras, M., Segura-Carretero, A., Mnayer, D., Sethi, G., Martorell, M., Abdull Razis, A. F., Sunusi, U., Kamal, R. M., Suleria, H. A. R. and Sharifi-Rad, J. (2021). <i>Nigella</i> Plants - Traditional uses, bioactive phytoconstituents, preclinical and clinical studies. <i>Front. Pharmacol.</i> , article 625386, https://doi.org/10.3389/fphar.2021.625386
11	Darand,,M Darabi,,Z Yari,,Z Saadati,,S Hedayati, ,,MKhonchek,,A Hosseini-Ahangar, ,,B Alavian,S. M. and Hekmatdoost .A. (٢٠١٩) , <i>Nigella sativa</i> and inflammatory biomarkers in patients with non-alcoholic fatty liver disease: Results from a randomized, double-blind, placebo-controlled, clinical trial. <i>Complement. Ther. Med.</i> , 44 : 204- 209.
12	Gheita, T. A. and Kenawy, S. K. (2012). Effectiveness of <i>Nigella sativa</i> oil in the management of rheumatoid arthritis patients: A placebo controlled study. <i>Phytother. Res.</i> , 26 : 1246-1248.
13	Hadi ,.V., Kheirouri, S ,Alizadiah,,M Khabbazi, A. and Hosseini, H. (2016). Effects of <i>Nigella sativa</i> oil extract on inflammatory cytokine response and oxidative stress status in patients

	with rheumatoid arthritis: a randomized, double-blind, placebo-controlled clinical trial. <i>Avicenna Journal of Phytomedicine</i> , 6 (1), 34 – 43.
14	Rahmani,,A Niknafs,,B Naseri,,M Nouri,M. and Tarighat-Esfanjani .A. (٢٠٢٢) ,Effect of <i>Nigella sativa</i> oil on oxidative stress, inflammatory, and glycemic control indices in diabetic hemodialysis patients: A randomized double-blind, controlled trial. <i>Evidence-Based Complementary and Alternative Medicine</i> . doi: 10.1155/2022/2753294.
15	Azizi, F., Ghorat, F., Rakhshani, M. H. and Rad, M. (2019). Comparison of the effect of topical use of <i>Nigella sativa</i> oil and diclofenac gel on osteoarthritis pain in older people: A randomized, double-blind, clinical trial. <i>Journal of Herbal Medicine</i> , 16 , http://dx.doi.org/10.1016/j.hermed.2019.100259
16	Salem, A. M., Bamosa, A. O., Qutub, H. O., Gupta, R. K., Badar, A., Elnour, A. and Afzal, M. N. (2017). Effect of <i>Nigella sativa</i> supplementation on lung function and inflammatory mediators in partly controlled asthma: a randomized controlled trial. <i>Ann. Saudi Med.</i> 37 , 64-71.
17	Braun, L. and Cohen, M. (2014). Herbs and Natural Supplements, Volume 2, an Evidence-Based Guide. 4 th edition. ISBN: 9780729541725.
18	The Therapeutic Goods Administration, Department of Health, Australian Government. https://myhealthbox.eu/en/view/3350321/bfc8fa27c1dc9d8d851be64a80e17a3e/leaflet .
19	https://www.webmd.com/vitamins/ai/ingredientmono-901/black-seed
20	https://www.rxlist.com/black_seed/supplements.htm
21	Boskabady, M. H. and Farhadi, J. (2008). The possible prophylactic effect of <i>Nigella sativa</i> seed aqueous extract on respiratory symptoms and pulmonary function tests on chemical war victims: A randomized, double-blind, placebo - controlled trial. <i>J. Altern. Complement. Med.</i> , 14 (9), 1137–1144.
22	Boskabady, M. H., Mohsenpoor, N. and Takaloo, L. (2010). Antiasthmatic effect of <i>Nigella sativa</i> in airways of asthmatic patients. <i>Phytomedicine</i> , 17 (10), 707-713.
23	Koshak, A., Wei, L., Koshak, E., Wali, S., Alamoudi, O., Demerdash, A., Qutub, M., Pushparaj, P. N. and Heinrich, M. (2017). <i>Nigella sativa</i> supplementation improves asthma control and biomarkers: A randomized, double-blind, placebo-controlled trial. <i>Phytother. Res.</i> , 31 : 403–409.
24	Tisserand, R. and Young, R. (2014). Essential Oil Safety. A Guide for Health Care Professionals, 2 nd ed. Churchill Livingstone. ISBN 978-0-443-06241-4.
25	<i>Nigella sativa</i> : Benefits, Side Effects and Medications. Articles https://www.pharmaonlinerox.com/nigella-sativa-benefits-side-effects-and-medications/
26	Rohman, A., Lukitaningsih, E., Rafi, M., Nurrulhidayah, A. F. and Windarsih, A. (2019). <i>Nigella sativa</i> oil: physico-chemical properties, authentication analysis and its antioxidant activity. <i>Food Research</i> , 3 (6): 628 - 634.