



Egyptian Herbal Monograph

Volume 3

Medicinal Plants used in Egypt

Egyptian Drug Authority (EDA)

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Actaea racemosa L.

كوهوش السوداء

1. Names & Synonyms (1)

Actaea racemosa L.

Family: Ranunculaceae.

Syns.: *Botrophis serpentaria* Raf., *Cimicifuga racemosa* L. Nutt., *Cimicifuga serpentaria* Pursh, *Macrotrys racemosa* L. Sweet, *Megotrys serpentaria* Raf., *Thalictrodes racemosa* L. Kuntze.

Arabic: kuhush alsawda كوهوش السوداء.

English: Black cohosh, Black snakeroot (2-4).

2. Parts used for medicinal purpose

Dried rhizomes and/or roots (2-8).

3. Major chemical constituents

Rhizomes and roots

- **Triterpenoid glycosides:** Cimicifugoside, actein, and 23-epi-26-deoxyactein (3) beside the aglycones of actein, deacetylactein, and 23-epi-26-deoxyactein (9-17).
- **Phenylpropanoid derivatives:** Caffeic acid derivatives (caffeic, ferulic and isoferulic acids) (9-17), and its condensation products; cimicifugic acids (e.g. fukinolic acid) (3, 13).
- **Flavonoids:** Kaempferol, biochanin A and genestein 4'-methyl ether (3, 18).
- **Alkaloids:** Quinoline and quinolizidine-type; anagyrine, baptifoline, magnoflorine, methyl cystine and methyl serotonin (19).
- **Others:** Salicylic acid (3), tannins, resin and fatty acids (20).

4. Medicinal uses (Indications)

- A. Relief of menopausal complaints such as hot flushes, profuse sweating, sleeping disorders, nervous irritability and depressive mood (2-8).
- B. Relief the pain associated with menstruation, premenstrual symptoms and in dysmenorrhoea (2, 6).

5. Herbal preparations correlated to medicinal use

1. Dry extract (3)

- 1.1. Extraction solvent ethanol 58% (V/V).
- 1.2. Extraction solvent ethanol 60% (V/V).
- 1.3. Extraction solvent propan-2-ol 40% (V/V).

2. Liquid (fluid) ethanolic extract (3, 4, 6, 21).

3. Tincture (1: 10 in 60% ethanol) (3, 4, 21).

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

A standardized black cohosh extract at a dose of 40- 80 mg, daily (standardized to contain 1 mg of triterpenes calculated as 27-deozyacetein per 20 mg of extract)

Preparation 1

Indications A and B

Adults: Equivalent to 40 - 2,400 mg, daily (6).

Indication A

Preparation 1.1

Adults: Single dose: 2.8 mg, 2 times daily. Daily dose: 5.6 mg (3, 5).

Preparation 1.2

Adults: Single dose: 6.5 mg, one single daily dose. Daily dose: 6.5 mg (2, 5).

Preparation 1.3

Adults: Single dose: 2.5 mg or 5.0 mg, 1-2 times, daily. Daily dose: 5.0 mg (3, 5).

Preparation 2

Indications A and B

Adults: Equivalent to 40 - 2,400 mg per daily (6).

20 drops, twice daily (60% ethanol V/V; equivalent to 40mg dried herb daily) (21).

Preparation 3

Indications A and B

Adults: 0.4 - 2 ml, 1-3 times daily (3, 4, 21-23) up to 4 ml, 3 times daily (4, 23).

Duration of use: It should not be taken for more than 6 months without medical advice (5).

Method of administration (5, 6): Oral use.

7. Contraindications

- Hypersensitivity to active substances and to other plants of the same family.
- Not be used by individuals with hormone-sensitive condition, such as breast cancer, endometriosis, uterine fibroids, ovarian cancer or uterine cancer, (3, 24) and in patients with cholestasis and celiac disease (4).

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.
- Patients with a history of liver disorder or liver diseases should consult a physician prior taking *Cimicifuga racemosae* preparations (5, 6).
- Patients should stop taking *Cimicifuga racemosae* preparations and consult their doctor immediately if they develop signs and symptoms suggestive of liver injury (tiredness, loss of appetite, yellowing of skin and eyes, severe upper stomach pain with nausea and vomiting or dark urine) (5, 6).
- In case of vaginal bleeding or other unclear symptoms, patients should consult their doctor (5).
- Treatment with black cohosh is not recommended to exceed six months (5, 25).

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

- **Antihypertensives:** Black cohosh increases the action of anti-hypertensives; concurrent use should be avoided (4, 26).
- **Docetaxel, doxorubicin:** Black cohosh may increase the toxicity of docetaxel and doxorubicin; concurrent use should be avoided (4).
- **Hormonal contraceptives:** Black cohosh may increase the effects; concurrent use should be avoided (4).
- **Hormone replacement therapy:** Black cohosh may alter the effects of other hormone replacement therapies; use together cautiously (4).
- **Sedatives/hypnotics:** Black cohosh may increase the hypotension; concurrent use should be avoided (4).
- **Tamoxifen:** Black cohosh may augment the anti-proliferative properties of tamoxifen (4).

10. Fertility, pregnancy and lactation

- The use during pregnancy and lactation is not recommended (5).
- No fertility studies available (5).

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 (5)

- If adverse reactions occur, a doctor or pharmacist should be consulted.
- **Hepatobiliary disorders:** Liver toxicity (including hepatitis, jaundice, disturbances in the liver function tests) is associated with the use of *Cimicifuga racemosae* containing products.
- **Skin and subcutaneous tissue disorders:** Allergic skin reactions (urticaria, itching, exanthema), facial oedema and peripheral oedema have been reported.
- **Gastrointestinal disorders:** Gastrointestinal symptoms (dyspeptic disorders, diarrhoea).

13. Overdose

- Large doses of black cohosh to be 5 g of the dried drug or 12 g of the fluid extract (27).
- Overdose has produced nausea and vomiting, vertigo and visual disturbances (23).

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

06/09/2022.

References

1	https://powo.science.kew.org .
2	WHO monographs on selected medicinal plants (2002). Monographs on Selected Medicinal Plants, 2 , 55- 65.
3	Barnes, J., Anderson, L. A. and Phillipson, J. D. (2007). Herbal Medicines, 3 rd edition. Published by the Pharmaceutical Press. ISBN 978 0 85369 623 0.
4	Skidmore-Roth, L. (2010). Mosby's Handbook of Herbs & Natural Supplements. 4 th ed. ISBN 9780323057417.
5	European Union herbal monograph on <i>Actaea racemosa</i> L. (2018). EMA/HMPC/48745/2017. Committee on Herbal Medicinal Products (HMPC).
6	Natural Health Product, <i>Actaea racemosa</i> L. (2018). Health Canada. http://webprod.hc-sc.gc.ca/nhp/nd/bdipsn/monoReq.do?id=44 .
7	ESCOPE Monographs (2018). <i>Cimicifuga racemosa</i> L. European Scientific Cooperative on Phytotherapy. Edited by Roberta Hutchins and Simon Mills..
8	Blumenthal, M., Brinckmann, J. and Wollschlaeger, B. (2003). The ABC Clinical Guide to Herbs, 1 st ed., American Botanical Council, Austin, Texas, USA.
9	Shao, Y., Harris, A., Wang, M., Zhang, H., Cordell, G. A., Bowman, M. and Lemmo, E. (2000). Triterpene glycosides from <i>Cimicifuga racemosa</i> . <i>J. Nat. Prod.</i> , 63 , 905-910.
10	Wende, K., Mugge, C., Thurow, K., Schopke, T. and Lindequist, U. (2001). Actaeaepoxide 3-O- β -D-xylopyranoside, a new cycloartane glycoside from the rhizomes of <i>Actaea racemosa</i> (<i>Cimicifuga racemosa</i>). <i>J. Nat. Prod.</i> , 64 , 986-989.
11	Bedir, E. and Khan, I. A. (2000). Cimicifugoside A: A new cyclolanostanol xyloside from the rhizome of <i>Cimicifuga racemosa</i> . <i>Chem. Pharm. Bull.</i> , 48 , 425-427.
12	Bedir, E. and Khan, I. A. (2001). A new cyclolanostanol arabinoside from the rhizome of <i>Cimicifuga racemosa</i> . <i>Pharmazie</i> , 56 , 268-269.
13	Nikolić, D., Lankin, D. C., Cisowska, T., Chen, S. N., Pauli, G.F. and van Breemen, R. B. (2015). Nitrogen-containing constituents of black Cohosh: Chemistry, structure elucidation, and biological activities. <i>Recent Adv. Phytochem.</i> , 45 , 31-75.
14	Chen, S. N., Li, W., Fabricant, D. S., Santarsiero, B. D., Mesecar, A., Fitzloff, J. F., Fong, H. H. and Farnsworth, N. R. (2002). Isolation, structure elucidation, and absolute configuration of 26-deoxyactein from <i>Cimicifuga racemosa</i> and clarification of nomenclature associated with 27-deoxyactein. <i>J. Nat. Prod.</i> , 65 , 601-605.
15	Watanabe, K., Mimaki, Y., Sakagami, H. and Sashida, Y. (2002). Cycloartane glycosides from the rhizomes of <i>Cimicifuga racemosa</i> and their cytotoxic activities. <i>Chem. Pharm. Bull.</i> , 50 , 121-125.
16	Kruse, S. O., Lohning, A., Pauli, G. F., Winterhoff, H. and Nahrstedt, A. (1999). Fukiic and piscidic acid esters from the rhizome of <i>Cimicifuga racemosa</i> and the in vitro estrogenic activity of fukinolic acid. <i>Planta Med.</i> , 65 , 763-764.

17	Chen, S. N., Fabricant, D. S., Lu, Z. Z., Zhang, H., Fong, H. H. and Farnsworth, N. R. (2002). Cimiracemates A-D, phenylpropanoid esters from the rhizomes of <i>Cimicifuga racemosa</i> . <i>Phytochemistry</i> , 61 , 409-413.
18	McCoy, J. and Kelly, W. (1996). Survey of <i>Cimicifuga racemosa</i> for phyto-estrogenic flavonoids. In: 212 th American Chemical Society National Meeting, Orlando, FL.
19	Mohapatra, S., Iqbal, A., Ansari, M.J., Jan, B., Zahiruddin, S., Mirza, M.A., Ahmad, S. and Iqbal, Z. (2022). Benefits of black cohosh (<i>Cimicifuga racemosa</i>) for women health: An up-close and in-depth review. <i>Pharmaceuticals</i> , 15 , 278. https://doi.org/10.3390/ph15030278 .
20	Barnes, J., Anderson, L. A. and Phillipson, J. D. (1996) Herbal Medicines: A Guide for Health-Care Professionals. The Pharmaceutical Press: London.
21	American Herbal Pharmacopoeia (1999). <i>Actaea racemosa</i> L. Analytical, Quality Control and Therapeutic Monograph. ISBN: 1-929425-04-X.
22	Pengelly, A. and Bennett, K. (2012). Appalachian Plant Monographs. Black cohosh, <i>Actaea racemosa</i> L. Published online at http://www.frostburg.edu/aces/appalachian-plants/ .
23	Braun, L. and Cohen, M. (2010). Herbs and Natural Supplements - An evidence-based guide. 3 rd edition, Churchill Livingstone. ISBN: 978 0 7295 3910 4.
24	https://www.webmd.verywellhealth.com/black-cohosh-888 .
25	Blumenthal, M., Busse, W. R., Hall, T., Goldberg, A., Grünwald, J., Riggins, C. W. and Rister, R. S. (1998). The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Translator: Klein S. Boston: <i>Integ. Med. Comm.</i> , 685 p. Translation of: German Kommission E.
26	PDR for Herbal Medicines (2002). Montvale, NJ: Medical Economics Company, 2 nd ed., ISBN 1-56363-361-2.
27	List, P. H. and Hörhammer, L. (1973). Hagers Handbuch der Pharmazeutischen Praxis. Berlin: Springer.