



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 June 2018
EMA/265439/2018

Black cohosh

Cimicifuga racemosa (L.) Nutt., rhizoma

This is a summary of the scientific conclusions reached by the Committee on Herbal Medicinal Products (HMPC) on the medicinal uses of black cohosh. The HMPC conclusions are taken into account by EU Member States when evaluating applications for the licensing of herbal medicines containing black cohosh.

This summary is not intended to provide practical advice on how to use medicines containing black cohosh. For practical information about using black cohosh medicines, patients should read the package leaflet that comes with the medicine or contact their doctor or pharmacist.

What is black cohosh?

Black cohosh is the common name for the root of the plant *Cimicifuga racemosa* (L.) Nutt.

The HMPC conclusions only cover black cohosh preparations that are obtained by putting the plant material in a solvent (such as ethanol) to dissolve compounds and form a liquid extract. The solvent is then evaporated to obtain a dry extract.

Herbal medicines containing black cohosh preparations are usually available in solid forms to be taken by mouth.

Black cohosh preparations may also be found in combination with other herbal substances in some herbal medicines. These combinations are not covered in this summary.

What are the HMPC conclusions on its medicinal uses?

The HMPC concluded that these black cohosh preparations can be used to treat menopausal complaints such as hot flushes and excessive sweating.

Black cohosh medicines should only be used in adult women and if symptoms continue or worsen whilst taking these medicines a doctor or pharmacist should be consulted. Black cohosh medicines should not be taken for longer than 6 months without consulting a doctor. Detailed instructions on how to take black cohosh medicines and who can use them can be found in the package leaflet that comes with the medicine.



What evidence supports the use of black cohosh medicines?

The HMPC conclusions on the use of these black cohosh medicines for menopausal complaints are based on their 'well-established use'. This means that there are bibliographic data providing scientific evidence of their effectiveness and safety when used in this way, covering a period of at least 10 years in the EU.

In its assessment, the HMPC considered around 20 clinical studies involving over 6,000 patients who received black cohosh. Results of the studies taken together indicate that black cohosh improves menopausal symptoms.

For detailed information on the studies assessed by the HMPC, see the HMPC assessment report.

What are the risks associated with black cohosh medicines?

Side effects with black cohosh medicines include liver problems, allergic skin reactions (such as rash and itchiness), swelling of the face and extremities, and symptoms affecting the gut such as indigestion and diarrhoea. The frequency of these side effects is unknown. Patients should stop taking black cohosh medicines and consult their doctor immediately if they develop symptoms suggestive of liver problems such as tiredness, loss of appetite, yellowing of skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine.

Further information on the risks associated with these black cohosh medicines, including the appropriate precautions for their safe use, can be found in the monograph under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use).

How are black cohosh medicines approved in the EU?

Any applications for the licensing of medicines containing black cohosh have to be submitted to the national authorities responsible for medicinal products, which will assess the application for the herbal medicine and take into account the scientific conclusions of the HMPC.

Information on the use and licensing of black cohosh medicines in EU Member States should be obtained from the relevant national authorities.

Other information about black cohosh medicines

Further information on the HMPC assessment of black cohosh medicines, including details of the Committee's conclusions, can be found under the tab 'All documents' on the Agency's website: [ema.europa.eu/Find medicine/Herbal medicines for human use](http://ema.europa.eu/Find%20medicine/Herbal%20medicines%20for%20human%20use). For more information about treatment with black cohosh medicines, read the package leaflet that comes with the medicine or contact your doctor or pharmacist.