

Press release

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MHRA action on safety concerns over Black Cohosh and liver injury

The Medicines and Healthcare products Regulatory Agency (MHRA) is concerned about links between black cohosh and the risk of liver disorders. Black cohosh, an ingredient of herbal products, is commonly used to treat menopausal symptoms and is widely available in the UK.

This link has been confirmed by the Commission on Human Medicines and the Herbal Medicines Advisory Committee. Both committees have reviewed all available data and concluded that the data underlines an association between black cohosh and risk of liver disorders.

Following advice from both committees, warnings are now to be added to the labels of black cohosh products and the MHRA is working with the herbal sector to ensure the public is fully informed about this potential risk.

Professor Philip Routledge, Chair of the Herbal Medicines Advisory Committee, emphasised: "After reviewing all available data, the Herbal Medicines Advisory Committee has come to the conclusion that black cohosh may be associated with liver disorders. This is rare, but can be serious."

Professor Kent Woods, MHRA Chief Executive, said: "In the light of this advice, the MHRA is working with the herbal sector to ensure that labels of black cohosh products carry updated safety warnings. The labels will point out the possible symptoms so that appropriate action can be taken without delay."

Notes to Editors:

1. The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines

and devices, and take any necessary action to protect the public promptly if there is a problem.

2. Adverse effects associated with the use of these products should be reported to the MHRA using the Yellow Card Reporting Scheme. www.yellowcard.gov.uk
3. It was estimated that in 2004 a total of 9 million treatment days were purchased.
4. Anyone who has previously experienced any liver complaint or any other serious health complaint is advised not to take *Black Cohosh* without speaking to their doctor first. It is important to always discuss all of the medication you are taking, including herbal products, with your doctor or herbal practitioner to ensure you receive the appropriate care.
5. Further information about herbal safety issues can be found on the MHRA website:
http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=93
6. There are many signs and symptoms of liver disease. Symptoms of liver problems include pain on the right side of the stomach just below the ribs, unexplained nausea (feeling sick), “flu-like” symptoms, dark urine and yellowing of eyes or skin (jaundice).

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