

## Notice Information: Human Medicines - Warning 20 July 2006

### Part 1. Product Information

- a) Title: Risk of serious hepatic (liver) toxicity with herbal medicinal products containing Cimicifugae Racemosae Rhizoma (Black Cohosh, root)
- b) Product Name/Type: Cimicifugae Racemosae Rhizoma (Black Cohosh, root)
- c) Active Substance: Cimicifugae Racemosae Rhizoma (Black Cohosh, root)
- d) Reference: EMEA Press Release
- e) Product Classification: Herbal Medicinal Product

### Part 2. Target Audience

- a) Target Audience: Patients, healthcare professionals.

### Part 3. Problem/Issue

- a) Problem/Issue: The European Medicines Agency (EMA) and the Committee on Herbal Medicinal Products (HMPC) have been made aware of a number of case reports of hepatotoxicity (liver injuries) in patients using Cimicifugae racemosae rhizoma (Black Cohosh, root). Following review of all available data, the HMPC considered that there is a potential connection between herbal medicinal products containing Cimicifugae racemosae rhizoma (Black Cohosh, root) and hepatotoxicity.

### Part 4. Background Information

a) Background Information:

Within the EU, Cimicifugae racemosae rhizoma (Black Cohosh, root) is widely used, sometimes in combination with other plants, in different licensed and unlicensed herbal medicinal products. The licensed products have a wide range of indications but Cimicifugae racemosae rhizoma (Black Cohosh, root) is currently most commonly used to treat minor climacteric (peri- and post-menopausal) symptoms such as hotflushes, sweating, sleep disturbances and nervous tension. In some Member States, Cimicifugae racemosae rhizoma (Black Cohosh, root) is also used in a range of other indications, such as: symptomatic relief of rheumatic pain, cough, stomach cramps, period pains/bloatedness, tenseness/irritability. The number of unlicensed herbal medicinal products containing Cimicifugae racemosae rhizoma (Black Cohosh, root) marketed in the Europe is not known. The HMPC evaluated 42 case reports of hepatotoxicity, collected from European National Competent Authorities (34 cases) as well as literature case reports (8 cases). Of these, only 16 cases were considered sufficiently documented<sup>1</sup> to allow the Committee to assess if use of Cimicifugae racemosae rhizoma (Black Cohosh, root) could be linked to the liver injuries. As a result of the assessment, 5 cases were excluded and 7 cases were considered unlikely to be related. In the remaining 4 cases (2 autoimmune hepatitis, 1 hepatocellular liver injury and 1 fulminant hepatic failure), there was a temporal association between the start of treatment with Cimicifugae racemosae rhizoma (Black Cohosh, root) and the occurrence of hepatic reaction. The HMPC will continue to review all new safety information relating to this issue and if necessary will release a further updated statement. Further details regarding the case reports are provided in the Annex 1: "Assessment of case reports connected to herbal medicinal product containing Cimicifugae racemosae rhizoma (Black Cohosh, root)", which can be found here.

## Part 5. Action to be taken

a) Action to be taken:

The EMEA therefore wishes to give the following advice to patients and healthcare professionals: Advice to patients: ¶ Patients should stop taking Cimicifugae racemosae rhizoma (Black Cohosh, root) and consult their doctor immediately if they develop signs and symptoms suggestive of liver injury (tiredness, loss of appetite, yellowing of the skin and eyes or severe upper stomach pain with nausea and vomiting or dark urine). ¶ Patients using herbal medicinal products should tell their doctor about it. Advice to healthcare professionals: ¶ Health care professionals are encouraged to ask patients about use of products containing Cimicifugae racemosae rhizoma (Black Cohosh, root). ¶ Suspected hepatic reactions should be reported to the national adverse reaction reporting schemes. Within the EU, Cimicifugae racemosae rhizoma (Black Cohosh, root) is widely used, sometimes in

## Part 6. Enquiries

- a) All enquiries should be made to:

To review the EMEA Press Statement in respect of this notice click here.

## Part 7. Keywords

- a) Keywords:

black cohosh Cimicifugae Racemosae Rhizoma (Black Cohosh, root)