



## **Black cohosh (*Cimicifuga racemosa*)**

### **New labelling and consumer information for medicines containing Black cohosh (*Cimicifuga racemosa*)**

9 February 2006

Black cohosh (*Cimicifuga racemosa*) has a long history of traditional use in North American Indian medicine and has been used widely in Western cultures since the early 1800s. It is generally used for the relief of the symptoms of menopause and is approved for use in Australia in medicines sold in pharmacies, supermarkets and other retail outlets.

The Therapeutic Goods Administration (TGA) recently reviewed the safety of Black cohosh (*Cimicifuga racemosa*) following reports of possible liver problems internationally and in Australia.

At the time of the review, there were 47 cases of liver reactions worldwide, including 9 Australian cases. In Australia, four patients were hospitalised, including two who required liver transplantation. Although some reports are confounded by multiple ingredients, by more than one medication or by other medical conditions, there is sufficient evidence of a causal association between Black cohosh and serious hepatitis.

However, considering the widespread use of Black cohosh, the incidence of liver reaction appears to be very low.

Following the safety review, the TGA has decided that medicines containing Black cohosh should include the following label statement:

"Warning: Black cohosh may harm the liver in some individuals. Use under the supervision of a healthcare professional".

New products will need to comply with the requirement from the time of manufacture. For existing products, a phase-in period of twelve (12) months will be given to allow sponsors adequate time to comply with the new labelling requirements.

#### **Symptoms of liver disease**

Symptoms of liver disease can include jaundice (yellowing of the skin or whites of the eyes), dark urine, nausea, vomiting, diarrhoea, weight loss, tiredness, appetite loss, fever, bloated abdomen or abdominal pain.

Consumers who experience any of these symptoms while taking, or after using, a Black cohosh product should seek medical advice. Consumers who have previously experienced any liver complaints should not take Black cohosh without consulting their doctor first.

It is important that consumers tell their doctor or pharmacist about all the medicines they are taking, including herbal or other complementary medicines.

The TGA also advises healthcare practitioners to be on the lookout for signs of liver toxicity associated with the use of Black cohosh medicines.