

A SYSTEMATIC REVIEW ON THE EFFICACY AND SAFETY OF *CIMICIFUGA RACEMOSA*

AVIELLO GABRIELLA¹, ERNST EDZARD², CAPASSO RAFFAELE¹, CAPASSO FRANCESCO¹, BORRELLI FRANCESCA¹

¹Department of Experimental Pharmacology, University of Naples Federico II, Via D. Montesano 49, 80131 Naples, Italy; ²Complementary Medicine, Peninsula Medical School, Universities of Exeter and Plymouth, 25 Victoria Park Road, Exeter EX2 4NT, UK

Background: Menopause generally occurs between the ages 45 and 55 years and it is characterized by the appearance of many symptoms. It has been estimated that in the world about 25 million women pass through menopause each year. The therapy used to reduce menopausal symptoms includes the use of herbal preparations such as black cohosh (*Cimicifuga racemosa*). The purpose of this update systematic review is to evaluate the clinical evidence for or against the efficacy and safety of black cohosh in providing relief of menopausal symptoms.

Methods: Six computerized database were searched to identify all clinical data that provided evidence on the efficacy and safety of *C. racemosa*. Only double-blind, controlled, randomized clinical trials (RCTs) were included in the evaluation of black cohosh efficacy. All clinical data including case reports and observational studies were included in the review of safety. No language restrictions were imposed.

Results: Six double-blind, controlled RCTs met our inclusion criteria. Moreover, three post-marketing surveillance studies, seven single case reports (four cases of liver damage, one case of seizure, one of muscle damage and one of cutaneous pseudolymphoma) and three case series (two cases of acute hepatitis, six cases of anaphylactic facio-oral oedemas and one of multiorgan failure) have been identified.

Interpretation: Overall RCTs do not consistently demonstrate an efficacy of black cohosh in reducing climacteric symptoms. Despite the presence of several case reports (principally case of liver damage), the causality of these events is seriously questioned. Since black cohosh has not yet been subjected to large-scale and long-term studies further post-marketing surveillance studies and long-term clinical studies are necessary to confirm its safety.