



## Effectiveness and safety of Black Cohosh extract for the treatment of menopausal symptoms

Black cohosh ( *cimicifuga racemosa* or *actaea racemosa*) has been used for many years by herbalists for the treatment of climacteric complaints.

Until recently there has been little quality research evidence to support the effectiveness of this therapy. However a study published in this year provides some evidence that Remifemin ®, a black cohosh extract, has short term therapeutic benefit.

Study title and publication details:

### Efficacy and Safety of Isopropanolic Black Cohosh Extract for Climacteric Symptoms

*Osmers R, Friede M, Liske E, Schnitker J, Freudenstein J, Henneicke-von Zepelin, H-H. Obstets Gynecol 2005;105: 1074-1083.*

The investigators who have reported their research findings conducted a study in which 290 women were randomly assigned to treatment with Remifemin ®, a black cohosh extract, or to placebo therapy for 12 weeks.

Effectiveness of therapy was assessed by the Menopause Rating Scale 1 Questionnaire which evaluates hot flushes, psyche (mood), soma ( cardiac complaints and joint and muscle symptoms) and atrophy ( sexuality, urinary complaints and vaginal dryness). Questionnaire scores for 'hot flushes', 'psyche' and 'atrophy' decreased significantly within the Remifemin® treated group compared to the placebo group.

No significant side effects of therapy over 12 weeks were reported.

This study provides some evidence for a therapeutic use of Remifemin®.

However it has some limitations:

Women were allowed to enter the study after only 4 weeks of traditional HT.

Many women do not experience recurrent symptoms after stopping HT for many weeks. This may have influenced the outcome, particularly if there was an imbalance between the two treatment groups in numbers of women who were recent HT users.

The study was of short duration and does therefore not provide evidence for longer term effectiveness and more importantly, long term safety. This is important as treatment for menopause is rarely limited to only 12 weeks of therapy. Reassurance regarding safety in particular would require a larger randomized controlled trial of at least 12 months duration.



The actual frequency and severity of hot flushes and night sweats was not reported in this study. Therefore we do not know whether all women who were recruited to this study had severe hot flushes at entry into the study, or that the severity of flushes was equal for women in both groups. Although a validated questionnaire was used, studies primarily evaluating effectiveness for treatment of hot flushes ideally include a daily diary record of both frequency and severity of hot flushes. As this was not done and thus true effect on flushes is not known.

Concern has been raised regarding the safety of black cohosh following the report of a single case of a 47 year old woman who developed acute hepatitis, and subsequently requiring a liver transplant after taking one week of what was allegedly a Black Cohosh preparation. However Remifemin® is in widespread use and other such cases have not been reported. The safety of black cohosh with respect to other hormone dependent tissues such as the breast and uterus with long term use still needs to be established.