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A systematic review of the safety of black cohosh.

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OBJECTIVE: To systematically review the available data relating to the safety of medicinal extracts of black cohosh (*Actaea racemosa*). **DESIGN:** Systematic literature searches were conducted in seven electronic databases, and the reference lists of all papers located were checked for further relevant publications. Information was also sought from the spontaneous reporting programs of the World Health Organization and national drug safety bodies. Sixteen manufacturers of black cohosh preparations were contacted and asked for data held on file. Finally, our own departmental files were searched. No language restrictions were imposed. Combination products and homeopathic preparations were excluded. **RESULTS:** Data from clinical studies and spontaneous reporting programs suggest that adverse events (AEs) with black cohosh are rare, mild, and reversible. Gastrointestinal upsets and rashes are the most common AEs. The spontaneous reporting programs do contain a few serious AEs, including hepatic and circulatory conditions, but causality cannot be determined. Although there is large amount of data investigating the efficacy of black cohosh, in particular the product Remifemin, safety issues and the monitoring of AEs have not been the focus. **CONCLUSION:** If black cohosh products are taken for a limited length of time, there seems to be a slight risk of mild, transient AEs. More serious AEs seem to be rare, and it is impossible to ascertain causality with black cohosh with the limited data available. Thus, although definitive evidence is not available, it would seem that black cohosh is a safe herbal medicine.

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