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Differentiated Evaluation of Extract-Specific Evidence on *Cimicifuga racemosa*'s Efficacy and Safety

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Evid Based Complement Alternat Med. 2013;2013:860602. Epub 2013 Aug 25.

Differentiated Evaluation of Extract-Specific Evidence on *Cimicifuga racemosa*'s Efficacy and Safety for Climacteric Complaints.

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Abstract

Past reviews on *Cimicifuga racemosa* (CR) without differentiation between extracts, quality, and indication altogether led to inconsistent data. Therefore, for the first time, we meet the requirements of the system's logic of **evidence**-based phytotherapy by taking into consideration extracts, pharmaceutical quality (reflected in a regulatory status as medicinal product), and indication. A literature search for clinical studies examining CR's **efficacy** and **safety** for menopausal **complaints** was conducted. The results were sorted by type of extract, regulatory status, and indication. Accordingly, Oxford Levels of **Evidence** (LOE) and Grades of Recommendation (GR) were determined. CR extracts demonstrated a good to very good **safety** in general, on estrogen-sensitive organs and the liver. However, only registered CR medicinal products were able to prove their **efficacy**. Best **evidence** was provided by the isopropanolic CR extract (iCR): the multitude of studies including more than 11,000 patients demonstrated consistent confirmatory **evidence** of LOE 1b (LOE 1a for **safety**) leading to GR A. The studies on the ethanolic extract BNO 1055 including more than 500 patients showed exploratory **evidence** of LOE 2b resulting in GR B. A positive benefit-risk profile is stated and limited to *Cimicifuga racemosa* products holding a marketing authorisation for treating **climacteric complaints**.

PMID: 24062793 [PubMed - as supplied by publisher] PMID: PMC3767045 [Free PMC Article](#)

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