

BLACK COHOSH

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

Note: Text in parentheses is additional optional information which can be included on the Product Licence Application and product labels at the applicants' discretion. The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: September 19, 2008

Proper name(s): *Actaea racemosa* L. (Ranunculaceae) (USDA 2006)

Common name(s): Black cohosh (McGuffin et al. 2000)

Source material(s): Root and rhizome (BHP 1996)

Route(s) of administration: Oral

Dosage form(s): Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s): Statement(s) to the effect of:

- ▶ (Traditionally) used in Herbal Medicine to help relieve the pain associated with menstruation (Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Ellingwood 1983 [1919]; Felter and Lloyd 1983 [1898]).
- ▶ (Traditionally) used in Herbal Medicine to help relieve muscle and joint pain associated with rheumatic conditions (such as rheumatoid arthritis, osteoarthritis and/or fibrositis), and of pain

- associated with neuralgia (such as sciatica) (Hoffmann 2003; BHP 1983; Ellingwood 1983 [1919]; Felter and Lloyd 1983 [1898]).
- ▶ (Traditionally) used in Herbal Medicine to help ease nervous tension (calmative) (Hoffmann 2003; Williamson 2003; BHP 1983; Ellingwood 1983 [1919]; Felter and Lloyd 1983 [1898]).
 - ▶ Used in Herbal Medicine to help relieve premenstrual symptoms (Blumenthal et al. 2000; Bradley 1992).
 - ▶ (Used in Herbal Medicine to) help(s) relieve symptoms associated with menopause (Raus et al. 2006; Wuttke et al. 2006; Frei-Kleiner et al. 2005; Blumenthal et al. 2000; Bradley 1992).

Note: Claims for traditional use must include the term “Herbal Medicine”.

Dose(s): Preparations equivalent to 40-2,400 mg dried root and rhizome, per day (Raus et al. 2006; Wuttke et al. 2006; Frei-Kleiner et al. 2005; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Ellingwood 1983 [1919])

See Appendix 1 for examples of dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration(s) of use: No statement required.

Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):

- ▶ Consult a health care practitioner if symptoms persist or worsen.
- ▶ Consult a health care practitioner prior to use if you are breastfeeding (Mills et al. 2006).
- ▶ Consult a health care practitioner prior to use if you have a liver disorder or develop symptoms of liver trouble (EMEA 2007; Lynch et al. 2006; Cohen et al. 2004; NIH 2004).

Contraindication(s): Do not use if you are pregnant (Brinker 2008; Hoffmann 2003; Tilgner 1999).

Known adverse reaction(s): No statement required.

Non-medicinal ingredients: Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the NHPD *Natural Health Products Ingredients Database*

Specifications:

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1: Monographs published in the U.S. Pharmacopoeia (USP)

Pharmacopoeia	Monograph
USP	Black Cohosh Black Cohosh Fluidextract Powdered Black Cohosh Powdered Black Cohosh Extract Black Cohosh Tablets

- ▶ Health Canada is aware of peer-reviewed published cases where products labelled as containing Black Cohosh were found by laboratory analysis to contain different species. In order to prevent misidentification, the identification of authentic Black Cohosh must be completed by an unambiguous validated method such as the HPLC-ELSD, HPLC-MS or HPLC-MS/MS to determine the presence of a specific marker compound and/or the absence of others. For example, *Actaea racemosa* contains the triterpene glycoside cimracemoside C (also called cimigenol-3-O-arabinoside), while most other *Actaea/Cimicifuga* species do not; conversely, other *Actaea/Cimicifuga* species contain the phenolic acid derivatives cimifugin and (or) cimifugin-3-O-glucoside (e.g. *A. cimicifuga* and *A. yunnanensis*, but not *A. dahurica*) while Black Cohosh does not. The commonly used markers, 23-*epi*-26-deoxyactein and actein, are found in more than one species of *Actaea* and therefore their presence is not sufficient evidence alone of the unambiguous identification of *Actaea racemosa* (Jiang et al. 2006; He et al. 2000). The NHPD recognizes that there are numerous methods which can be used to unambiguously identify Black Cohosh. These methods include, but are not limited to, those cited in the following references: Avula et al. 2007; He et al. 2006; Jiang et al. 2006; Brigham et al. 2004; Zerega et al. 2002; He et al. 2000.

Note: Data relating to the identification of Black Cohosh, using an unambiguous validated method, is not to be submitted with the compendial Product Licence Application, although it may be requested at the NHPD’s discretion.

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Appendix 1: Examples of appropriate dosage preparations and frequencies of use

Dried root and rhizome:

- ▶ 40 mg, per day (Blumenthal et al. 2000)
- ▶ 40 to 200 mg, per day (Bradley 1992)

Decoction: 40 to 200 mg dried root and rhizome, per day (Bradley 1992)

Fluidextract:

- ▶ 40 mg dried equivalent, per day
(1:1, 40-60% alcohol, 0.04 ml) (Blumenthal et al. 2000)
- ▶ 300 to 2,000 mg dried equivalent, per day
(1:1, alcohol, 0.3-2 ml) (Williamson et al. 1988)
- ▶ 300 to 1,800 mg dried equivalent, per day
(1:1, 0.3-1.8 ml (5 to 30 minims)) (Ellingwood 1983 [1919])

Tincture:

- ▶ 400-800 mg dried equivalent, 3 times per day
(1:5, 60% alcohol, 2-4 ml) (Hoffmann 2003)
- ▶ 40 mg dried equivalent, per day
(1:10, 40-60% alcohol, 0.4 ml) (Blumenthal et al. 2000)
- ▶ 40 to 200 mg dried equivalent, per day
(1:10, 60% alcohol, 0.4 to 2 ml) (Bradley 1992)
- ▶ 200 to 400 mg dried equivalent, per day
(1:10, 2-4 ml) (Williamson et al. 1988)
- ▶ 185 to 370 mg dried equivalent, per day
(1:10, 1.85 to 3.7 ml (0.5-1 dram)) (Ellingwood 1983 [1919])

Dried aqueous or ethanolic extract:

- ▶ 40 mg dried equivalent, per day (Frei-Kleiner et al. 2006)
- ▶ 40 mg dried equivalent, per day (Raus et al. 2006)
- ▶ 20 mg dried equivalent, 2 times per day (Wuttke et al. 2006)