

NATURAL HEALTH PRODUCT

BLACK COHOSH - *ACTAEA RACEMOSA*

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

Notes

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

Date

August 28, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Actaea racemosa</i>	<ul style="list-style-type: none"> ▶ Black bugbane ▶ Black cohosh ▶ Black snakeroot 	<i>Actaea racemosa</i>	<ul style="list-style-type: none"> ▶ Rhizome ▶ Root ▶ Root and rhizome 	Dried

References: Proper name: USDA 2018; Common names: McGuffin et al. 2000; Source material: BHP 1996.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



Use(s) or Purpose(s)

- ▶ (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, Felter and Lloyd 1983).
- ▶ (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 pain associated with neuralgia (such as sciatica) (Hoffmann 2003, BHP 1983, Ellingwood 1983, Felter and Lloyd 1983).
- ▶ (Traditionally) used in Herbal Medicine to help ease nervous tension (calmative) (Hoffmann 2003, Williamson 2003, BHP 1983, Ellingwood 1983, Felter and Lloyd 1983)
- ▶ 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).

The following combined use(s) or purpose(s) is/are also acceptable:

Used in Herbal Medicine to help relieve the pain associated with menstruation as well as premenstrual symptoms (Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Ellingwood 1983; Felter and Lloyd 1983).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

40 - 2,400 milligrams of dried root and/or 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).

Direction(s) for use

No statement required.



Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

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

Contraindication(s)

Do not use this product if you are pregnant (Brinker 2010; Hoffmann 2003; Tilgner 1999).

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.
- ▶ 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 cimiracemoside 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*-26deoxyactein 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 NNHPD 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 NNHPD's discretion.

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