

Black Cohosh

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Black Cohosh - *Actaea Racemosa* (PDF Version - 74 KB) 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 label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label. Date January 31, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) *Actaea racemosa* Black bugbane Black cohosh Black snakeroot *Actaea racemosa* Rhizome Root Root and rhizome Dry References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Source information: 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. 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 (as a calmative) to help ease nervous tension (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 (EMA 2018; Raus et al. 2006, Wuttke et al. 2006, Frei-Kleiner et al. 2005, Blumenthal et al. 2000, Bradley 1992). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help relieve muscle and join pain associated with rheumatic conditions, pain associated with neuralgia, and to help ease nervous tension). For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. Black cohosh is traditionally used in Herbal Medicine to help ease nervous tension). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardised Extracts (Dry extract*, Tincture, Fluid Extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 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). *Note: Solvents allowed for the method of preparation "Non-standardized extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Direction(s) for use No statement required. Duration of Use No statement required. Risk Information Caution(s) and Warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a liver disorder or develop symptoms of liver trouble (EMA 2018, 2007; Lynch et al. 2006; Mills et al. 2006; Cohen et al. 2004; NIH 2004). Contraindication(s) Do not use 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 Condition(s) Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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 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) cimifigin-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 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Avula B, Ali Z, Khan IA. Chemical Fingerprinting of *Actaea racemosa* (Black Cohosh) and its comparison study with closely related *Actaea* species (*A. pachypoda*, *A. podocarpa*, *A. rubra*) by HPLC. *Chromatographia* 2007;66(9/10):757-762. BHP 1983: British Herbal Pharmacopoeia. Bournemouth (UK): British Herbal Medical Association. BHP 1996: British Herbal Pharmacopoeia. Bournemouth (UK): The British Herbal Medicine Association. Blumenthal M, Goldberg A, Brinkmann J, editors. *Herbal Medicine: Expanded Commission E Monographs*. Boston (MA): Integrative Medicine Communications; 2000. 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Available from: http://www.ema.europa.eu/en/documents/herbal-report/assessment-case-reports-connected-herbal-medicinal-products-containing-cimicifugae-racemosae-rhizoma-black-cohosh-root_en.pdf Felton HW, Lloyd JU. *King's American Dispensatory*, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983. [Reprint of 1898 original]. Frei-Kleiner S, Schaffner W, Rahlfs VW, Bodmer C, Birkhäuser M. *Cimicifuga racemosa* dried ethanolic extract in menopausal disorders. *Maturitas* 2005;51(4):397-404. Gardner Z, McGuffin M, editors. *American Herbal Products Association's Botanical Safety Handbook*. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013. 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DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and Warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a liver disorder or develop symptoms of liver trouble (EMA 2018, 2007; Lynch et al. 2006; Mills et al. 2006; Cohen et al. 2004; NIH 2004). Contraindication(s) Do not use if you are pregnant (Brinker 2010; Hoffmann 2003; Tilgner 1999). Known Adverse Reaction(s) No statement required.

| Proprietary name(s) | Common name(s) | Source information | | |
|------------------------|--|------------------------|-----------------------------|--|
| Source material(s) | Part(s) | Preparation(s) | | |
| <i>Actaea racemosa</i> | Black bugbaneBlack cohoshBlack snakeroot | <i>Actaea racemosa</i> | RhizomeRootRoot and rhizome | |