

Bilberry - Oral

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BILBERRY - VACCINIUM MYRTILLUS - Oral Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 51.3 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 the PLA and product 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. Date October 25, 2024 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) Vaccinium myrtillus Bilberry European blueberry Huckleberry Whortleberry Vaccinium myrtillus Fruit Dry References: Proper name: USDA 2023; Common names: Gardner and McGuffin 2013; Source information: Blumenthal et al. 2000. Route of Administration Oral (Blumenthal et al. 2000) 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 as an astringent to help relieve diarrhoea (ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000; Grieve 1971; Felter and Lloyd 1983). Source of antioxidants/Provides antioxidants (Upton 2001; Mills and Bone 2000) Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Upton 2001; Mills and Bone 2000). Used in Herbal Medicine to help slow the progression of disorders of the eye, such as diabetic and hypertensive retinopathy, and macular degeneration (Mills and Bone 2005; Blumenthal 2003; Upton 2001; Morazzoni and Bombardelli 1996). Used in Herbal Medicine to help relieve symptoms related to non-complicated chronic venous insufficiency (CVI), such as sensation of swelling, heaviness and tingling of the legs (Barnes 2007; Mills and Bone 2005; ESCOP 2003; Upton 2001). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Used in Herbal Medicine to help slow the progression of disorders of the eye, such as diabetic and hypertensive retinopathy, and macular degeneration and to help relieve symptoms related to non-complicated chronic venous insufficiency (CVI), such as sensation of swelling, heaviness and tingling of the legs). 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. Bilberry is traditionally used in Herbal Medicine as an astringent to help relieve diarrhoea). 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) Slowing the progression of disorders of the eye and relieving symptoms related to non-complicated CVI Methods of preparation: Standardized extracts (Dry extract) 160 - 480 milligrams of dried extract standardized to 36% anthocyanins, per day; Not to exceed 160 milligrams per single dose (USP-NF 2023; Blumenthal 2003; ESCOP 2003; Upton 2001). Antioxidant Methods of preparation: Dry, Dry standardized, Powdered, Powdered standardized, Standardized and Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Not to exceed 75 grams of dried fruit, per day (USP-NF 2023; Barnes 2007; ESCOP 2003; Blumenthal et al. 2000; Grieve 1971). Standardized preparations only: not to exceed 36% anthocyanins. All other uses Methods of preparation: Dry, Dry standardized, Powdered, Powdered standardized, Standardized and Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 1.8 - 75 grams of dried fruit, per day (USP-NF 2023; Barnes 2007; ESCOP 2003; Blumenthal et al. 2000; Grieve 1971). Standardized preparations only: not to exceed 36% anthocyanins Direction(s) for use No statement required. Duration(s) of Use No statement

required. Risk Information Caution(s) and warning(s) Relief of diarrhoea Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Slowing the progression of disorders of the eye and to relieve symptoms related to non-complicated CVI Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen. Contraindication(s) No statement required. 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 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (GB): The Pharmaceutical Press. Blumenthal M. 2003. ABC Clinical Guide to Herbs. New York (NY): Thieme. Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. ESCOP 2003: European Scientific Cooperative on Phytotherapy Scientific Committee. 2003. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme. Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 2, 18 th edition. Sandy (OR): Eclectic Medical Publications [Reprint of 1898 original]. Gardner Z, McGuffin M. editors. 2013. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. Boca Raton (FL): CRC Press. Grieve M. 1971. A Modern Herbal, Volume 1. New York (NY): Dover Publications [Reprint of 1931 Harcourt, Brace & Company publication]. Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Churchill Livingstone. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. Morazzoni P, Bombardelli E. 1996. Vaccinium myrtillus L. Fitoterapia 67(1):3-29. Upton R, editor. 2001. American Herbal Pharmacopoeia and Therapeutic Compendium: Bilberry Fruit Vaccinium myrtillus L.: Standards of Analysis, Quality Control and Therapeutics. Santa Cruz (CA): American Herbal Pharmacopoeia. USDA 2023: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). – Global. U.S. National Plant Germplasm System. [Accessed 2023 December 27]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> USP-NF 2023: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2023. References Reviewed Brinker F. 2001. Herb Contraindications and Drug Interactions, 3 rd edition. Sandy (OR): Eclectic Medical Publications. Canter PH, Ernst E. 2004. Anthocyanosides of Vaccinium myrtillus (bilberry) for night vision - a systematic review of placebo-controlled trials. Survey of Ophthalmology 49(1):38-50. Jang YP, Zhou J, Nakanishi K, Sparrow JR. 2005. Anthocyanins protect against A2E photooxidation and membrane permeabilization in retinal pigment epithelial cells. Photochemistry and Photobiology 81(3):529-536. Lee J, Lee HK, Kim CY, Hong YJ, Choe CM, You TW, Seong GJ. 2005. Purified high-dose anthocyanoside oligomer administration improves nocturnal vision and clinical symptoms in myopia subjects. British Journal of Nutrition 93:895-899. Levy Y, Glovinski Y. 1998. The effect of anthocyanosides on night vision. Eye 12:967-969. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press. Muth ER, Laurent JM, Jasper P. 2000. The effect of bilberry nutritional supplementation on night vision acuity and contrast sensitivity. Alternative Medicine Review 5(2):164-173. Sparrow JR, Vollmer-Snarr HR, Zhou J, Jang PY, Jockusch. 2003. A2E-epoxides damage DNA in retinal pigment epithelial cells. Journal of Biological Chemistry 278(20):18207-18213. Steigwalt RD Jr, Gianni B, Paolo M, Bombardelli E, Burki C, Schönla F. 2008. Effects of Mirtogenol® on ocular blood flow and intraocular hypertension in asymptomatic subjects. Molecular Vision 14:1288-1292. Zadok D, Levy Y, Glovinski Y. 1999. The effect of anthocyanosides in multiple oral dose on night vision. Eye 13:734-736. Report a problem on this page Date modified: 2019-03-01

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) Relief of diarrhoea Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Slowing the progression of disorders of the eye and to relieve symptoms related to non-complicated CVI Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen. Contraindication(s) No statement required. 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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Vaccinium myrtillus	BilberryEuropean blueberryHuckleberryWhortleberry	Vaccinium myrtillus	Fruit	Dry