

Bearberry - *Arctostaphylos uva-ursi*

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Bearberry - *Arctostaphylos Uva-Ursi* (PDF Version - 59 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 June 3, 2019 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) *Arctostaphylos uva-ursi* Bearberry Kinnikinnick *Uva ursi* *Arctostaphylos uva-ursi* Leaf Dried references 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 any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) Traditionally used in Herbal Medicine as a mild diuretic to help relieve symptoms associated with minor urinary tract infections, such as burning sensation and/or frequent urination (BHP 1983; Grieve 1971; Felter 1922; Ellingwood 1919; Felter and Lloyd 1898). Used in Herbal Medicine to help relieve symptoms associated with minor urinary tract infections, such as burning sensation and/or frequent urination (EMA 2016; Godfrey and Saunders 2010; Hoffman 2003). 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) Traditionally used in Herbal Medicine (traditional claim) Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 0.3 - 1.33 grams of dried leaves, 2 to 3 times per day (Newall 1996; Bradley 1992; BHP 1983; Felter 1922; Ellingwood 1919; Felter and Lloyd 1898). Method of preparation: Decoction 1.7 - 4 grams of dried leaves per day; not to exceed 1.33 grams of dried leaves per single dose (EMA 2016; WHO 2002; Blumenthal 2000; Newall 1996; Bradley 1992; BHP 1983; Felter and Lloyd 1898). Used in Herbal Medicine (non-traditional claim) Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 0.3 - 1.33 grams of dried leaves, 2 to 3 times per day (Newall 1996; Bradley 1992; BHP 1983; Felter 1922; Ellingwood 1919; Felter and Lloyd 1898). Method of preparation: Decoction 1.7 - 4 grams of dried leaves per day; not to exceed 1.33 grams of dried leaves per single dose (EMA 2016; WHO 2002; Blumenthal 2000; Newall 1996; Bradley 1992; BHP 1983; Felter and Lloyd 1898). Methods of preparation: Standardized Extracts (Dry Extract) 500 - 700 milligrams of dry extract standardized to 20% - 30% of Arbutin, 2 to 4 times per day (EMA 2016; ESCOP 2003; WHO 2002; Blumenthal 2000). Note The standardized dry extract dose is equivalent to 100-210 milligrams of Arbutin, 2 to 4 times per day. Direction(s) for use Take a few hours before or after any medication or natural health product (Brinker 2018; Mills and Bone 2000). Do not take with highly acidic foods (e.g. citrus fruits and juice) or medications, which may acidify urine (ESCOP 2003; Duke 2002; WHO 2002; Brinker 2001; Blumenthal 2000; Mills and Bone 2000; Bradley 1992). Duration(s) of Use Products providing 60 milligrams or more of dried leaves and/or products providing 20 milligrams or more of Arbutin, per day For occasional use only. Consult a health care practitioner/health care provider/health care professional/doctor/ physician for use beyond 1 week (EMA 2016; WHO 2002; Brinker 2001; Blumenthal 2000; Mills and Bone 2000; Bradley 1992). Risk Information Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Products providing 60 milligrams or more of dried leaves and/or products providing 20 milligrams or more of Arbutin, per day Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a liver disorder, fever, painful urination (dysuria), spasms, or blood in urine (EMA 2016; Duke 2002; Newall 1996). Contraindication(s) Do not use this product if you are pregnant or breastfeeding (Brinker 2018; EMA 2016; ESCOP 2003; WHO 2002; Brinker 2001; Blumenthal 2000; Mills and Bone 2000; Bradley 1992). 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. References Cited BHP 1983: British Herbal Medicine Association's Scientific Committee. British Herbal Pharmacopoeia. Bournemouth (GB): The British Herbal Medicine Association; 1983. Blumenthal M, Goldberg A, Brinckmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Newton (MA): Integrative Medicine Communications; 2000. Bradley PR, editor. British Herbal Compendium Volume 1: A Handbook of Scientific Information on Widely Used Plant Drugs - Companion Volume 1 of the British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1992. Brinker F. 2018. Final updates and additions for Herb Contraindications and Drug Interactions, 4th edition. including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Accessed 2019 May 17]. Available from: <https://www.eclecticherb.com/herb-contraindications-drug-interactions> Brinker F. Herb Contraindications and Drug Interactions. 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001. Dr. Duke's Phytochemical and Ethnobotanical Databases. [Accessed 2019 May 17]. Available from: <https://phytochem.nal.usda.gov/phytochem/search/list> Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; 1998 [Reprint of 1919 original]. EMA 2016: EMA/HMPC/573460/2009 Rev. 1. Uvae ursi folium. London (GB): European Medicines Agency: Committee on Herbal Medicinal Products (HMPC); 2016 October 14. [Accessed 2019 May 17]. Available from: <https://www.ema.europa.eu/en/medicines/herbal/uvae-ursi-folium> E/S/C/O/P 2003: European Scientific Cooperative of Phytotherapy. E/S/C/O/P Monographs: The Scientific Foundation for Herbal Medicinal Products, Second edition completely revised and expanded. Exeter (GB): European Scientific Cooperative on Phytotherapy; 2003. Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1922 original]. Felter HW, Lloyd JU. King's American Dispensatory. Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Felter HW, Lloyd JU. King's American Dispensatory. Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Godfrey A, Saunders PR, Barlow K, Gilbert C, Gowan M, Smith F. Principles and Practices of Naturopathic Botanical Medicine, Volume 1: Botanical Medicine Monographs. Toronto (ON): CCNM Press; 2010. Grieve, M. A Modern Herbal, Volume 2. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. Mills S, Bone K. Principles and Practice of Phytotherapy, Modern Herbal Medicine. Edinburgh (GB): Churchill Livingstone; 2000 Newall CA, Anderson LA, Phillipson JD. Herbal Medicines: A guide for health-care professionals. London (GB): The Pharmaceutical Press; 1996 USDA 2019: ARS, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Arctostaphylos uva-ursi*. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 May 17]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx> WHO 2002: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 3. Geneva (CH): World Health Organization; 2002. References Reviewed EMEA 2012b: EMA/HMPC/573465/2009 Rev. 1. Assessment report on *Arctostaphylos uva-ursi* (L.) Spreng., folium. London (GB): European Medicines Agency: Committee on Herbal Medicinal Products (HMPC); 2012 January 24. [Accessed 2012 February 29]. Available from: https://www.ema.europa.eu/en/documents/herbal-report/superseded-assessment-report-arctostaphylos-uva-ursi-l-spreng-folium-revision-1_en.pdf Gardner and McGuffin. Botanical Safety Handbook second edition. American Herbal Products Association. CRC Press. Taylor and Francis Group 2013. HC 2011: Health Canada. Canada Vigilance Adverse Reaction Online Database. Ottawa (ON): Marketed Health Products Directorate, Health Canada; 2011. [Accessed 2012 February 28]. Available from: <http://webprod3.hc-sc.gc.ca/arquery-rechercheei/index-eng.jsp> Sayre LE. A Manual of Organic Materia Medica and Pharmacognosy [Internet] 4th edition. Philadelphia (PA): P. Blakiston's Son & Co.; 1917. Scanned by Michael Moore, director, The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2012 March 28]. Available from: <http://www.swsbm.com/SayreMM/SayreMM.html> Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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

DOSAGE FORM(S)

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

RISK INFORMATION

Caution(s) and warning(s) All products Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Products providing 60 milligrams or more of dried leaves and/or products providing 20 milligrams or more of Arbutin, per day Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a liver disorder, fever, painful urination (dysuria), spasms, or blood in urine (EMA 2016; Duke 2002; Newall 1996). Contraindication(s) Do not use this product if you are pregnant or breastfeeding (Brinker 2018; EMA 2016; ESCOP 2003; WHO 2002; Brinker 2001; Blumenthal 2000; Mills and Bone 2000; Bradley 1992). 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)

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.

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation(s)		
Arctostaphylos uva-ursi	BearberryKinnikinnickUva ursi	Arctostaphylos uva-ursi	Leaf	Dried