



NATURAL HEALTH PRODUCT

BEARBERRY – *Arctostaphylos uva-ursi*

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

December 8, 2015

Proper name(s)

Arctostaphylos uva-ursi (L.) Spreng (Ericaceae) (USDA 2014)

Common name(s)

- ▶ Bearberry (USDA 2014)
- ▶ Uva-ursi (USDA 2014)

Source material(s)

Leaf (Grieve 1971; Felter 1922)

Route(s) of administration

Oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to, capsules, chewables (e.g. tablets), liquids, powders, strips or tablets.
- ▶ 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 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; Felten 1922; Ellingwood 1919; Felten 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 (EMEA 2012a; Godfrey and Saunders 2010; Hoffman 2003).

Note

A claim for traditional use must include the term “Herbal Medicine.”

Dose(s) Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

All uses or purposes

Dry, powder, tincture, fluid extract

0.6 – 4 g dried leaves per day, in 2 or 3 divided doses; providing up to 1.33 g dried leaves per single dose (Newall 1996; Bradley 1992; BHP 1983; Felten 1922; Ellingwood 1919; Felten and Lloyd 1898).

Decoction

1.7 – 4 g dried leaves per day, in 2 or 3 divided doses; providing up to 1.33 g dried leaves per single dose (EMEA 2012a; WHO 2002; Blumenthal 2000; Newall 1996; Bradley 1992; BHP 1983; Felten and Lloyd 1898).

Used in Herbal Medicine (non-traditional use)

All standardized extracts

Dose equivalent to 100 – 210 mg anhydrous arbutin, 2 to 4 times per day; providing a maximum of 840 mg anhydrous arbutin per day (EMEA 2012a; ESCOP 2003; WHO 2002; Blumenthal 2000).

Note



See Appendix 1 for examples of appropriate dosage preparations according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Directions for use

- ▶ Take a few hours before or after any medication or natural health product (Brinker 2010; 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 of use

Statement(s) to the effect of

Preparations equivalent to ≥ 60 mg dried leaves and/or preparations equivalent to ≥ 20 mg anhydrous arbutin per day

For occasional use only. Consult a health care practitioner for use beyond one week (EMEA 2012a; WHO 2002; Brinker 2001; Blumenthal 2000; Mills and Bone 2000; Bradley 1992).

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

All products

If symptoms persist or worsen, consult a health care practitioner.

Preparations equivalent to ≥ 60 mg dried leaves and/or preparations equivalent to ≥ 20 mg anhydrous arbutin per day

If you have a liver disorder, fever, painful urination (dysuria), spasms, or blood in urine, consult a health care practitioner prior to use (EMEA 2012a; Duke 2002; Newall 1996).

Contraindication(s)

If you are pregnant or breastfeeding, do not use this product (EMEA 2012; Brinker 2012; 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 Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited

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Appendix 1 Examples of appropriate dosage preparations for standardised extracts

Dry extract (Extract ratio 3.5-5.5:1), 60% ethanol extraction, quantified to 23.5-29.3% hydroquinone derivatives calculated as anhydrous arbutin: Dose is equivalent to 100-210 mg of anhydrous arbutin, 2 to 4 times per day (EMEA 2012a).

Dry extract (Extract ratio 2.5-4.5:1), water extraction, quantified to 20-28% hydroquinone derivatives calculated as anhydrous arbutin. Dose is equivalent to 100-210 mg of anhydrous arbutin, 2 to 4 times per day (EMEA 2012a).