

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

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)
<i>Arctostaphylos uva-ursi</i>	<ul style="list-style-type: none"> ▶ Bearberry ▶ Kinnikinnick ▶ Uva ursi 	<i>Arctostaphylos uva-ursi</i>	Leaf	Dried

References: Proper name: USDA 2019; Common names: USDA 2019; Source material: Grieve 1971, Felter 1922.

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 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.

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