BILBERRY

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

Note: Text in parentheses is additional optional information which can be included on the PLA and product labels at the applicant’s discretion. The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: June 8, 2010

Proper name(s): Vaccinium myrtillus L. (Ericaceae) (USDA 2006)

Common name(s): Bilberry (McGuffin et al. 2000)

Source material(s): Fruit/Berry (Blumenthal et al. 2000)

Route(s) of administration:

- Oral (Blumenthal et al. 2000)
- Buccal (Blumenthal et al. 2000)

Dosage form(s):

Oral: The acceptable pharmaceutical dosage forms include, but are not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons. This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Buccal: Those dosage forms suited to buccal administration

Use(s) or Purpose(s): Statement(s) to the effect of:

Oral:
(Traditionally) used in Herbal Medicine as an astringent (Mills and Bone 2000; Grieve 1971 [1931]; Felter and Lloyd 1983 [1898]) to help relieve diarrhoea (ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000; Grieve 1971 [1931]; Felter and Lloyd 1983 [1898]).

Provides antioxidants (Upton 2001; Mills and Bone 2000) for the maintenance of good health.

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).

**Buccal:**

Used in Herbal Medicine to help relieve mild inflammations of the mucous membranes of the mouth and/or throat (ESCOP 2003; Blumenthal et al. 2000).

**Dose(s):**

**Oral:**

For slowing the progression of disorders of the eye and relieving symptoms related to non-complicated CVI:

Preparations containing a dried extract standardized to 36% anthocyanosides/anthocyanins, equivalent to 12-75 g fruit, per day (USP 32; Blumenthal 2003; ESCOP 2003; Upton 2001)

For all other oral uses: Preparations equivalent to 1.8-75 g dried fruit, per day (USP 32; Barnes 2007; ESCOP 2003; Blumenthal et al. 2000; Grieve 1971 [1931])

**Buccal:**

Decoction: 5-10 g dried fruit (Blumenthal et al. 2000)

**Directions for use:**

Place crushed dried fruit in 150 ml cold water. Bring to a boil for approximately 10 minutes. Strain while hot. Dilute one part decoction with 10 parts water (ESCOP 2003; Blumenthal et al. 2000)

Rinse and/or gargle as needed.
See Appendix 1 for examples of dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration of use:** No statement required.

**Risk information:** Statement(s) to the effect of:

**Caution(s) and warning(s):**

For relief of diarrhoea and relief of mild inflammations of the mucous membranes of the mouth and/or throat: Consult a health care practitioner if symptoms persist or worsen.

For slowing the progression of disorders of the eye and to relieve symptoms related to non-complicated CVI: Consult a health care practitioner if symptoms worsen.

**Contraindication(s):** No statement required.

**Known adverse reaction(s):** No statement required.

**Non-medicinal ingredients:** Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

**Specifications:**

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1: Monographs published in the British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.) and the U.S. Pharmacopeia (USP)

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
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<tbody>
<tr>
<td>BP</td>
<td>Dried Bilberry</td>
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<tr>
<td>Ph. Eur.</td>
<td>Bilberry Fruit, Dried</td>
</tr>
<tr>
<td></td>
<td>Fresh Bilberry Fruit Dry Extract, Refined and Standardised</td>
</tr>
<tr>
<td>USP</td>
<td>Powdered Bilberry Extract</td>
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</tbody>
</table>
References cited:


**References reviewed:**


Appendix 1: Examples of dosage preparations, frequencies of use and directions for use

Oral:

Dried fruit:
- 20-60 g dried fruit, per day (Barnes 2007; ESCOP 2003; Blumenthal 2003)
- 4 g powdered dry fruit, per day (Grieve 1971 [1931])

Decoction: 5-10 g dried fruit, 4-6 times per day (Blumenthal et al. 2000)

**Directions for use:** Place crushed dried fruit in 150 ml of cold water. Bring to a boil for approximately 10 minutes. Strain while hot. Drink cold several times per day (Blumenthal et al. 2000).

Fluidextract:
- 2-4 g dried equivalent, 3 times per day (1:1, 2-4 ml) (Blumenthal et al. 2000)
- 1.8-7.4 g dried equivalent, per day (1:1, 1.8-7.4 ml (0.5-2 drachms)) (Grieve 1971 [1931])

Cold macerate: 5-10 g dried fruit, 4-6 times per day (Blumenthal et al. 2000)

**Directions for use:** Soak crushed dried fruit in 150 ml cold water for 2 hours, allowing the fruit to swell. Drink cold several times per day (Blumenthal et al. 2000).

Standardized extract:
- 80-160 mg dry extract of bilberry fruit, standardized to 25% anthocyanidins, 3 times per day (Blumenthal 2003)
- 340-480 mg extract of bilberry fruit, standardized to 36% anthocyanins, per day (ESCOP 2003)
- 160-480 mg powdered extract, in divided doses, standardized to 25% anthocyanidins, per day (Upton 2001)

Buccal:

Decoction: 10% decoction of dried fruit (ESCOP 2003; Blumenthal et al. 2000)