NATURAL HEALTH PRODUCT

BLUEBERRY

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

February 7, 2014

Proper name(s)

- Vaccinium corymbosum L. (USDA 2010a)
  and/or
- Vaccinium angustifolium Aiton (USDA 2011)
  and/or
- Vaccinium pallidum Aiton (USDA 2010b)

Common name(s)

Blueberry (USDA 2010a,b,2011)

Source material(s)

Fruit (USDA 2010a,b,2011)

Route(s) of administration

Oral

Dosage form(s)

- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, 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

Provides antioxidants (Serafini et al. 2009; Kolosova et al. 2004).

Dose(s)

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Dry, Non-Standardized extracts & Standardized extracts

• Up to 20 g Quantity Crude Equivalent (QCE), per day (CNF 2010; McAnulty et al. 2004).
• Up to 150 g fresh fruit, per day (CNF 2010; McAnulty et al. 2004).

Note
When submitting by ePLA, choose fresh for original material field and indicate approximate value of fresh:dry ratio (e.g. 7:1).

Duration of use

No statement required.

Risk information
Statement(s) to the effect of

Caution(s) and warning(s)

Products providing ≥ 5 g QCE per day; Products providing ≥ 37.5 g fresh fruit per day

If you are taking blood thinners, consult a health care practitioner prior to use (ASHP 2005; Franco et al. 2004; IOM 2001; Hansten et al. 1997).

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* (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 NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

**References cited**


McAnulty SR, McAnulty LS, Nieman DC, Dumke CL, Morrow JD, Utter AC, Henson DA, Proulx WR, George GL. Consumption of blueberry polyphenols reduces exercise induced oxidative stress compared to vitamin C. Nutrition Research 2004;24:209-221.


References reviewed


