Health Canada Santé Canada

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).

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