

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 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 on the label.

Date

January 31, 2025

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Vaccinium angustifolium</i>	<ul style="list-style-type: none"> • Blueberry • Late sweet blueberry • Lowbush blueberry • Low sweet blueberry • Sweethurts • Upland lowbush blueberry 	<i>Vaccinium angustifolium</i>	Fruit	<ul style="list-style-type: none"> • Fresh • Dry
<i>Vaccinium corymbosum</i>	<ul style="list-style-type: none"> • American blueberry • Blueberry • Highbush blueberry • Swamp blueberry 	<i>Vaccinium corymbosum</i>		
<i>Vaccinium pallidum</i>	<ul style="list-style-type: none"> • Blueberry • Hillside lowbush blueberry 	<i>Vaccinium pallidum</i>		

References: Proper names: USDA 2024a,b,c; Common names: USDA 2024a,b,c; Source information: USDA 2024a,b,c.

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 oral use are indicated in the dosage form drop-down list of the web-based Product licence Application form for Compendial applications.

Use(s) or Purpose(s)

- Source of antioxidants/Provides antioxidants (Serafini et al. 2009; Kolosova et al. 2004).
- Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Serafini et al. 2009; Kolosova et al. 2004).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

- Not to exceed 20 grams of dried fruit, per day (CNF 2025; McAnulty et al. 2004).
- Not to exceed 150 grams of fresh fruit, per day (CNF 2025; McAnulty et al. 2004).

Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

Extracts providing up to 40 % Anthocyanins and not to exceed 195 milligrams Anthocyanins, per day and a Quantity crude equivalent of 20 grams of dried fruit or 150 grams of fresh fruit, per day (CNF 2025; McAnulty et al. 2004; Prior et al. 1998).

Direction(s) for use

No statement required.

Combination rules

- The medicinal ingredients in Table 1 can be combined if the total quantity of dried fruits does not exceed 20 g or if the total quantity of fresh fruits does not exceed 150 g.



- Dried and fresh fruits cannot be combined as part of this monograph.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Products providing 5 grams or more of total dried fruit, per day; Products providing 37.5 grams or more of total fresh fruit, per day; Products providing 5 grams or more of total dried and fresh fruit, per day

Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (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 Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

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.



EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredient in each capsule <i>Vaccinium pallidum</i> (Blueberry) X:1 extract Equivalent to YY g dried fruit; Providing ZZ% Anthocyanins	XX mg
Uses <ul style="list-style-type: none"> • Source of antioxidants. • Source of antioxidants that help protect cell against free radicals. 	
Warnings <p>If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame</p> <p>Ask a health care practitioner before use if you are taking blood thinners².</p>	
Directions Adults 18 years and older: Take X capsule(s), X time(s) per day.	
Other information (Add storage information).	
Non-medicinal ingredients List all NMIs.	
Questions? (Call) 1-XXX-XXX-XXXX	

¹This section can be removed from the table if the product contains no allergen or aspartame

²Products providing 5 grams or more of dried fruit, per day.

References cited

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USDA 2024a: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. *Vaccinium corymbosum* (L). [Accessed 2024 February 13]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

USDA 2024b: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. *Vaccinium pallidum* Aiton. [Accessed 2024 February 13]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

USDA 2024c: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. *Vaccinium angustifolium* Aiton. [Accessed 2024 February 13]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

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