Health Canada Santé Canada

NATURAL HEALTH PRODUCT

WHITE KIDNEY BEAN EXTRACT

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 April 29, 2022

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)
Phaseolus vulgaris	White kidney bean	*Phaseolus vulgaris*	Seed	Dry

References: Proper name: Barrett and Udani 2011, Wu et al. 2010, Udani et al. 2009, Vinson et al. 2009, Celleno et al. 2007, Udani and Singh 2007, Udani et al. 2004, Rothacker 2003, Facciola 1998; Common name: Barrett and Udani 2011, Wu et al. 2010, Udani et al. 2009, Vinson et al. 2009, Celleno et al. 2007, Udani and Singh 2007, Udani et al. 2004, Rothacker 2003, Facciola 1998; Source information: USDA 2019.

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)

- Provides support for healthy (postprandial) glucose metabolism (within two hours after a meal) (Barrett and Udani 2011; Udani et al. 2009; Vinson et al. 2009; Boivin et al. 1987; Layer et al. 1986).
- Helps improve (postprandial) glucose metabolism (within two hours after a meal) (Barrett and Udani 2011; Udani et al. 2009; Vinson et al. 2009; Boivin et al. 1987; Layer et al. 1986).
- Helps reduce the (enzymatic) digestion of carbohydrates (Barrett and Udani 2011; Vinson et al. 2009; Boivin et al. 1987; Layer et al. 1986; Layer et al. 1985).
- To be used with a program of reduced intake of dietary calories and increased physical activity (if possible) to help in weight management (Udani et al. 2018; Grube et al 2014; Wu et al. 2010; Celleno et al. 2007; Udani and Singh 2007; Udani et al. 2004; Rothacker 2003).

The following combined use(s) or purpose(s) is/are also acceptable:

Helps reduce the (enzymatic) digestion of carbohydrates and improve (postprandial) glucose metabolism (within two hours after a meal) (Barrett and Udani 2011; Udani et al. 2009; Vinson et al. 2009; Boivin et al. 1987; Layer et al. 1986; Layer et al. 1985).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Standardized aqueous extracts (Extract dry)

Glucose metabolism; Carbohydrate digestion

1.5 - 3 grams of white kidney bean extract per day, standardized to 3,000 AAIU[1] of alpha-amylase inhibitors, per gram of extract[2] (Barrett and Udani 2009; Udani et al. 2009; Vinson et al. 2009; Layer et al. 1985).

Weight management

1 gram of white kidney bean extract, three times per day, standardized to 3,000 AAIU[1] of alpha-amylase inhibitors per gram of extract (Udani et al. 2018; Grube et al 2014; Wu et al. 2010; Celleno et al. 2007; Udani and Singh 2007; Udani et al. 2004; Rothacker 2003).

Notes:
[1]AAIU = alpha-amylase inhibiting units.
[2]The potency quantity should be equal to 3,000 AAIU of alpha-amylase inhibitors per gram of extract. For example, if the quantity of the extract per dosage unit is listed as 500 mg, the

quantity of alpha-amylase inhibitors should be 1,500 AAIU or if the quantity of the extract is 1,500 mg per dosage unit, the quantity of alpha-amylase inhibitors should be 4,500 AAIU, etc.

Direction(s) for use

Take before meals (Udani et al. 2018; Grube et al 2014; Wu et al. 2010; Barrett and Udani 2009; Udani et al. 2009; Vinson et al. 2009; Celleno et al. 2007; Udani and Singh 2007; Udani et al. 2004; Rothacker 2003; Layer et al. 1985).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you are breastfeeding.
- Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use if you have diabetes (Buse 2000).

Contraindication(s)

Do not use this product if you are pregnant.

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* (NHPR).

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.
- Amount of hemagglutinating units (HU) should not exceed 645 HU per gram.
- Amount of trypsin inhibitor units (TIU) should not exceed 20 TIU per milligram.

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