

White Kidney bean extract

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White Kidney Bean Extract Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 202 K) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA s) 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; Layer et al. 1985; Boivin et al. 1987; Layer et al. 1986). 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 AAU 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 AAU 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 AAU = alpha-amylase inhibiting units. 2 The potency quantity should be equal to 3,000 AAU 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 AAU or if the quantity of the extract is 1,500 mg per dosage unit, the quantity of alpha-amylase inhibitors should be 4,500 AAU, 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. References cited Barrett ML, Udani JK. A proprietary alpha-amylase inhibitor from white bean (*Phaseolus vulgaris*): A review of clinical studies on weight loss and glycemic control. *Nutrition Journal* 2011;10:24. Boivin M, Zinsmeister AR, Go VL, DiMagno EP. Effect of a purified amylase inhibitor on carbohydrate metabolism after a mixed meal in healthy humans. *Mayo Clinic Proceedings* 1987;62:249-255. Buse J. A symposium: combining insulin and oral agents. *The American Journal of Medicine* 2000;108:23S-32S. Celleno L, Tolaini MV, D'Amore A, Perricone NV, Preuss HG. A dietary supplement containing standardized *Phaseolus vulgaris* extract influences body composition of overweight men and women. *International Journal of Medical Sciences* 2007;4(1):45-52. Facciola S. *Cornucopia II: A source book of edible plants*. Vista (CA): Kampong Publications, 1998. Grube B, Chong W-F, Chong P-W, Riede L. Weight reduction and maintenance with IQP-PV-101: A 12-week randomized controlled study with a 24-week open label period. *Obesity* 2014; 22:645-651. Layer P, Carlson GL and DiMagno EP. Partially purified white bean amylase inhibitor reduces starch digestion in vitro and inactivates intraduodenal amylase in humans. *Gastroenterology* 1985;88:1895-902. Layer P, Zinsmeister AR, DiMagno EP. Effects of decreasing intraluminal amylase activity on starch digestion and postprandial gastrointestinal function in humans. *Gastroenterology* 1986;91:41-48. Rothacker D. Reduction in body weight with a starch blocking diet aid: Starch Away comparison with placebo. Leiner Health Products. 2003. [Internet]. [Accessed 2021 October 20]. Udani JK, Hardy M, Madsen DC. Blocking carbohydrate absorption and weight loss: a clinical trial using Phase 2 brand proprietary fractionated white bean extract. *Alternative Medicine Review* 2004;9(1):63-69. Udani JK, Singh BB. Blocking carbohydrate absorption and weight loss: a clinical trial using a proprietary fractionated white bean extract. *Alternative Therapies* 2007;13(4):32-37. Udani JK, Singh BB, Barrett ML, Preuss HG. Lowering the glycemic index of white bread using a white bean extract. *Nutrition Journal* 2009;8:52. Udani J, Tan, O, Molina J. Systematic Review and Meta-Analysis of a Proprietary Alpha-Amylase Inhibitor from White Bean (*Phaseolus vulgaris* L.) on Weight and Fat Loss in Humans. *Foods* 2018; 7(4), 63. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. *Phaseolus vulgaris*. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2021 October 20]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx> Vinson JA, Kharrat HA, Shuta D. Investigation of an amylase inhibitor on human glucose absorption after starch consumption. *The Open Nutraceuticals Journal* 2009;2:88-91. Wu X, Xu X, Shen J, Perricone N, Preuss H. Enhanced weight loss from a dietary supplement containing standardized *Phaseolus vulgaris* extract in overweight men and women. *Journal of Applied Research* 2010;10:73-79. References reviewed Erner S, Meiss D. The effect of Thera-Slim™ on weight, body composition and select laboratory parameters in adults with overweight and mild - moderate obesity. [Internet]. [Accessed 2021 October 20]. Koike T, Koizumi Y, Tang L, Takahara K, Saitou Y. The antiobesity effect and the safety of taking "Phaseolamin 1600 diet". *J New Rem & Clin (Japanese)* 2005;54:1-16. Osorio L, Gamboa J. Random multi-center evaluation to test the efficacy of *Phaseolus vulgaris* (Precarb) in obese and overweight individuals. 2005. Thom E. A randomized, double-blind, placebo-controlled trial of a new weight-reducing agent of natural origin. *Journal of International Medical Research* 2000;28:229-233. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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).

DOSAGE FORM(S)

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.

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 theNatural Health Products Regulations(NHPR).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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.

REFERENCES

Route of administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Phaseolus vulgaris	White kidney bean	Phaseolus vulgaris	Seed	Dry