



## NATURAL HEALTH PRODUCT

### WHITE KIDNEY BEAN EXTRACT – *PHASEOLUS VULGARIS* L. 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 the statements are synonymous. Either term or statement may be selected by the applicant.

**Date** January 12, 2016

#### Proper name(s)

*Phaseolus vulgaris* L. (USDA 2010)

#### Common name(s)

White kidney bean extract (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 material(s)

Seed

#### 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 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).
- ▶ Could be a complement to a healthy lifestyle that incorporates a calorie-reduced diet and regular physical activity for individuals involved in a weight management program (Wu et al. 2010; Celleno et al. 2007; Udani and Singh 2007; Udani et al. 2004; Rothacker 2003).

**Dose(s)** Statement(s) to the effect of

**Subpopulation(s)**

Adults ( $\geq 18$  years)

**Quantity(ies)**

*All claims except weight management*

1.5-3 g aqueous extract per day, standardised to 3000 alpha-amylase inhibiting units (AAIU) per gram (Barrett and Udani 2009; Udani et al. 2009; Vinson et al. 2009; Layer et al. 1985).

*Weight management*

1 g aqueous extract, standardised to 3000 alpha-amylase inhibiting units (AAIU) per gram, three times per day (Wu et al. 2010; Celleno et al. 2007; Udani and Singh 2007; Udani et al. 2004; Rothacker 2003).

Note: Solvent used for extraction must be water only. On the electronic PLA form, indicate 'Extract dry standardized' as a method of preparation and 'Water 100%' in the solvent field.

**Directions for use**

Take before meals (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 of use**

No statement required.



### **Risk information**

Statement(s) to the effect of

#### **Caution(s) and warning(s)**

- ▶ If you are breastfeeding, consult a health care practitioner prior to use.
- ▶ If you have diabetes, consult a health care practitioner prior to use (Buse 2000).

#### **Contraindication(s)**

If you are pregnant, do not use this product.

#### **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**

No statement required.

### **Specifications**

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate 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.

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 2012 April 3]. Available from: [http://www.phase2info.com/pdf/Phase2\\_Study6.pdf](http://www.phase2info.com/pdf/Phase2_Study6.pdf).

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.

USDA 2010: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. National Germplasm Resources Laboratory, Beltsville (MD). [*Phaseolus vulgaris*. Last updated 2010 August 19; Accessed 2013 April 17]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl)



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 2012 April 3]. Available from: [http://www.phase2info.com/pdf/Phase2\\_Study8.pdf](http://www.phase2info.com/pdf/Phase2_Study8.pdf)

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. Available from: [http://www.phase2info.com/pdf/Phase2\\_Study10.pdf](http://www.phase2info.com/pdf/Phase2_Study10.pdf)

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.