

Beta-Glucan

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BETA-GLUCAN 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 - 137 KB) 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 February 23, 2024 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 beta-Glucan beta-Glucan beta-D-Glucan Avena sativa Hordeum vulgare Seed Seed bran Isolate Oat beta-Glucan Avena sativa References: Proper name: Charlton et al. 2012; EFSA 2011a,b, 2010; Queenan et al. 2007; Braaten et al. 1994; Uusitupa et al. 1992; Common names: Charlton et al. 2012; EFSA 2011a,b, 2010; Queenan et al. 2007; Braaten et al. 1994; Uusitupa et al. 1992; Source information: USDA 2023; Charlton et al. 2012; Queenan et al. 2007. 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) Helps reduce/lower LDL cholesterol (which is one risk factor for the development of coronary heart disease) (Charlton et al. 2012; EFSA 2011a,b,2010; AbuMweiss et al. 2010; HC 2010; Wolever et al. 2010; Delahoy et al. 2009; Queenan et al. 2007; Wood 2007; Biorklund et al. 2005; NECP 2002; Brown et al. 1999; Ripsin et al. 1992). Helps reduce/lower bad cholesterol (which is one risk factor for the development of coronary heart disease) (Charlton et al. 2012; EFSA 2011a,b, 2010; AbuMweiss et al. 2010; HC 2010; Wolever et al. 2010; Delahoy et al. 2009; Queenan et al. 2007; Wood 2007; Biorklund et al. 2005; NECP 2002; Brown et al. 1999; Ripsin et al. 1992). Provides support for healthy (postprandial) glucose metabolism (within two hours after a meal) (EFSA 2011a,b; Ulmuis et al. 2011; Granfeldt et al. 2008; Panahi et al. 2007; Biorklund et al. 2005; Kabir et al. 2002). Helps improve (postprandial) glucose metabolism (within two hours after a meal) (EFSA 2011a,b; Ulmuis et al. 2011; Granfeldt et al. 2008; Panahi et al. 2007; Biorklund et al. 2005; Kabir et al. 2002). Source of fiber for the maintenance of good health (CFIA 2022; IOM 2005). Helps support and maintain a healthy digestive system (CFIA 2022; IOM 2005). Note: The above uses can be combined on the product label (e.g., Helps reduce/lower bad cholesterol and improve glucose metabolism). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 2 - 10 grams of beta-Glucan, per day (Charlton et al. 2011; EFSA 2011a,b, 2010; AbuMweiss et al. 2010; Queenan et al. 2007; IOM 2005; Johnston et al. 1998; Braaten et al. 1994; Torronen et al. 1992; Uusitupa et al. 1992). Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) No statement required. 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. References Cited AbuMweis SS, Jew S, Ames NP. Beta-glucan from barley and its lipid lowering capacity: a meta-analysis of randomized, controlled trials. *European Journal of Clinical Nutrition* 2010;64:1472-1480. 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MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

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.

DOSE(S)

Maki KC, Galant R, Samuel P, Tesser J, Witchger MS, Ribaya-Mercado JD, Blumberg JB, Geohas J. Effects of consuming foods containing oat beta-glucan on blood pressure, carbohydrate metabolism and biomarkers of oxidative stress in men and women with elevated blood pressure. European Journal of Clinical Nutrition 2007;61(6):786-795. Maki KC, Shinnick F, Seeley MA, Veith PE, Quinn LC, Hallissey PJ, Temer A, Davidson MH. Food products containing free tall oil-based phytosterols and oat beta-glucan lower serum total and LDL cholesterol in hypercholesterolemic adults. Journal of Nutrition 2003;133(3):808-813. Morimoto T, Ogawa M, Orita K, Sugimachi K, Toge T, Dohi K, Nomura Y, Monden Y, Ogawa N. Postoperative adjuvant randomized trial comparing chemoendocrine therapy, chemotherapy and immunotherapy for patients with stage II breast cancer: 5-year results from the Nishinohon Cooperative Study Group of Adjuvant Chemoendocrine Therapy for Breast Cancer (ACETBC) of Japan. European Journal of Cancer 1996;32A(2):235-242. Nakazato H, Koike A, Saji S, Ogawa N, Sakamoto J. Efficacy of immunochemotherapy as adjuvant treatment after curative resection of gastric cancer. Study Group of Immunochemotherapy with PSK for Gastric Cancer. Lancet 1994;343(8906):1122-1126. Naumann E, van Rees AB, Onning G, Oste R, Wydra M, Mensink RP. Beta-glucan incorporated into a fruit drink effectively lowers serum LDL-cholesterol concentrations. American Journal of Clinical Nutrition 2006;83(3):601-605. Ohno N, Terui T, Chiba N, Kurachi K, Adachi Y, Yadomae T. Resistance of highly branched (1- ->3)-beta-D-glucans to formolysis. Chemical & Pharmaceutical Bulletin (Tokyo) 1995;43(6):1057-1060. Onning G, Wallmark A, Persson M, Akesson B, Elmstahl S, Oste R. Consumption of oat milk for 5 weeks lowers serum cholesterol and LDL cholesterol in free-living men with moderate hypercholesterolemia. Annals of Nutrition & Metabolism 1999;43(5):301-309. Othman RA, Moghadasian MH, Jones PJH. Cholesterol-lowering effects of oat b-glucan. Nutrition Reviews 2011;69(6):299-309. Parrish FW, Perlin AS, Reese ET. Selective enzymolysis of polyb-D-glucan and structure of the polymers. Canadian Journal of Chemistry 1960;38(11):2094-2104. Pick ME, Hawrysh ZJ, Gee MI, Toth E, Garg ML, Hardin RT. Oat bran concentrate bread products improve long-term control of diabetes: a pilot study. Journal of the American Dietetic Association 1996;96(12):1254-1261. Ramakers JD, Volman JJ, Biorklund M, Onning G, Mensink RP, Plat J. Fecal water from ileostomic patients consuming oat beta-glucan enhances immune responses in

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RISK INFORMATION

Caution(s) and warning(s) No statement required. 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 CONDITION(S)

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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation		
beta-Glucan	beta-Glucan beta-D-Glucan	Avena sativa Hordeum vulgare	Seed Seed bran	Isolate
Oat beta-Glucan	Avena sativa			