Chitosan

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CHITOSAN 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 - 50.2 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 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 November 29, 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) Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose Chitosan Poliglusam Crab Krill Shrimp Exoskeleton Clam Oyster Shell References: Proper name: Sweetman 2011; Common names: Sweetman 2011; Source information: Sweetman 2011; Dutta et al. 2004. 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 lower blood total (and LDL (low density lipoprotein)) cholesterol (Bokura and Kobayashi 2003; Tai et al. 2000). Helps lower bad cholesterol (Bokura and Kobayashi 2003; Tai et al. 2000). Helps maintain healthy cholesterol levels (EFSA 2011; Mhurchu et al. 2004). 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 (Moraru et al. 2018; Willers et al. 2012; Jull et al. 2008; Mhurchu et al. 2005). Notes: The above uses can be combined on the product label (e.g., Helps lower blood total and LDL cholesterol and maintain healthy cholesterol levels). The terms 'Helps' or 'Helps to' can be used interchangeably on the label. Restrictions when this monograph is combined with other monographs (Class II and III applications): If a weight management claim is made: Weight management is a long-term process and must therefore, be associated with a long-term intervention. Medicinal ingredient with diuretic properties may be included in weight management products, however no diuretic claim can be applied as it is associated with a short-term duration of use (occasional use only). Stimulant laxatives cannot be present at therapeutic dose in weight management products as their short term duration of use is not compatible with the duration of use for weight management. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 0.5 - 3 grams of chitosan, 2 times per day (Mhurchu et al. 2004; Bokura and Kobayashi 2003; Tai et al. 2000). Direction(s) for use Take with meals (Bokura and Kobayashi 2003). Take a few hours before or after taking other medications or health products since the absorption of these products may be affected (Kubbinga et al. 2015). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Pittler et al. 1999). All products (except for weight management) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Weight management Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Contraindication(s) All products Do not use if you have an allergy to seafood. Weight management Do not use if you are pregnant (HC 2010). Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Moraru et al. 2018; Mhurchu et al. 2004; Pittler et al. 1999). 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. The degree of deacetylation for chitosan should be above 75%. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Bokura H, Kobayashi S. Chitosan decreases total cholesterol in women: a randomized,

doubleblind, placebo-controlled trial. European Journal of Clinical Nutrition 2003;57(5):721-725. Dutta PK, Dutta J, Tripathi VS. Chitin and chitosan: Chemistry, properties and applications. Journal of Scientific & Industrial Research 2004;63:20-31. EFSA 2011: European Food Safety Authority. SCIENTIFIC OPINION: Scientific Opinion on the substantiation of health claims related to chitosan and reduction in body weight (ID 679, 1499), maintenance of normal blood LDL-cholesterol concentrations (ID 4663), reduction of intestinal transit time (ID 4664) and reduction of inflammation (ID 1985) pursuant to Article 13(1) of Regulation (EC) No 1924/20061; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), European Food Safety Authority (EFSA), Parma, Italy. [Accessed 2024 March 7]. Available from: http://www.efsa.europa.eu/en/efsajournal/doc/2214.pdf HC 2010: Health Canada: Prenatal Nutrition Guidelines for health Professionals: Gestational weight gain [Accessed 2024 April 7]. Available from: https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/fn-an/alt_formats/pdf/nutrition/prenatal/ewba-mbsa-eng.pdf Jull AB, Ni Mhurchu C, Bennett DA, Dunshea-Mooj CAE, Rodgers A. Chitosan for overweight or obesity (review). The Cochrane Collaboration; John Wiley and Sons Ltd; 2008. Kubbinga M, Nguyen MA, Staubach P, Teerenstra S, Langguth P. The influence of chitosan on the oral bioavailability of Acyclovir - a comparative bioavailability study in humans. Pharmaceutical Research 2015; 32:2241-2249. Mhurchu CN, Poppitt SD, McGill AT, Leahy FE, Bennett DA, Lin RB, Ormrod D, Ward L,Strik C, Rodgers A. (on behalf of the Effect of Chitosan on Health and Obesity (ECHO) Collaboration). The effect of the dietary supplement, Chitosan, on body weight: a randomised controlled trial in 250 overweight and obese adults. International Journal of Obesity 2004;28: 1149-1156. Moraru C, Mincea MM, Frandes M, Timar B, Ostafe V. A Meta-Analysis on Randomised Controlled Clinical Trials Evaluating the Effect of the Dietary Supplement Chitosan on Weight Loss, Lipid Parameters and Blood Pressure. Medicina (Kaunas) 2018; 54(6):109. Pittler MH, Abbot NC, Harkness EF, Ernst E. Randomized, double-blind trial of chitosan for body weight reduction. European Journal of Clinical Nutrition 1999;53(5):379-381. Sweetman SC, editor. 2011. Martindale: The Complete Drug Reference, 37th edition. London (GB): Pharmaceutical Press. Tai TS, Sheu WH, Lee WJ, Yao HT, Chiang MT. Effect of chitosan on plasma lipoprotein concentrations in type 2 diabetic subjects with hypercholesterolemia. Diabetes Care 2000;23(11):1703-1704. Willers J, Plotz SC, Hahn A. The combination of a high-protein formula diet and polyglucosamine decreases body weight and parameters of glucose and lipid metabolism in overweight and obese men and women. European Journal of Food Research and Review 2012; 2(1):29-45. References Reviewed Ausar SF, Morcillo M, Leon AE, Ribotta PD, Masih R, Vilaro Mainero M, Amigone JL, Rubin G, Lescano C, Castagna LF, Beltramo DM, Diaz G, Bianco ID. Improvement of HDL- and LDLcholesterol levels in diabetic subjects by feeding bread containing chitosan. Journal of Medicinal Food 2003;6(4):397-399. European Bioinformatics Institute. Chitosan (CHEBI: 16261). European Molecular Biology Laboratory. 2023. [Accessed 2024 March 7]. Available from: https://www.ebi.ac.uk/chebi/searchId.do?chebiId=CHEBI:16261 Kaats GR, Michalek JE, Preuss HG. Evaluating efficacy of a chitosan product using a doubleblinded, placebo-controlled protocol. Journal of the American College of Nutrition 2006;25: 389-394. Maezaki Y, Tsuji K, Nakagawa Y, Kawai Y, Akimoto M. Hypocholesterolemic effect of chitosan in adult males. Bioscience, Biotechnology, and Biochemistry 1993;57(9):1439-1444. Metso S, Ylitalo R, Nikkilä M, Wuolijoki E, Ylitalo P, Lehtimäki T. The effect of long-term microcrystalline chitosan therapy on plasma lipids and glucose concentrations in subjects with increased plasma total cholesterol: a randomised placebo-controlled double-blind crossover trial in healthy men and women. European Journal of Clinical Pharmacology 2003;59:741-746. Schiller RN, Barrager E, Schauss AG, Nichols EJ. A randomized double blind placebo controlled study examining the effects of a rapidly soluble chitosan dietary supplement on weight loss and body composition in overweight and mildly obese individuals. Journal of the American Nutraceutical Association 2001;4(1):42-49. Tapola NS, Lyyra ML, Kolehmainen RM, Sarkkinen ES, Schauss AG. Safety aspects and cholesterol-lowering efficacy of chitosan tablets. Journal of the American College of Nutrition 2008;27(1):22-30. Wuolijoki E, Hirvela T, Ylitalo P. Decrease in serum LDL cholesterol with microcrystalline chitosan. Methods & Findings in Experimental & Clinical Pharmacology 1999;21(5):357-361. Ylitalo R, Lehtinen S, Wuolijoki E, Ylitalo P, Lehtimaki T. Cholesterol-lowering properties and safety of chitosan. Arzneimittelforschung 2002;52(1):1-7. Zhang J, Xia W, Liu P, Cheng Q, Tahirou T, Gu W, Li B. Chitosan Modification and Pharmaceutical/Biochemical Applications, Marine Drugs 2010;8:1962-1987. 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.

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) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Pittler et al. 1999). All products (except for weight management) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Weight management Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Contraindication(s) All products Do not use if you have an allergy to seafood. Weight management Do not use if you are pregnant (HC 2010). Known adverse reaction(s) When using this product you may experience gastrointestinal discomfort/disturbances (Moraru et al. 2018; Mhurchu et al. 2004; Pittler et al. 1999).

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 theNatural 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.The degree of deacetylation for chitosan should be above 75%.

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose	ChitosanPoliglusam	CrabKrillShrimp	Exoskeleton
ClamOyster	Shell		