

NATURAL HEALTH PRODUCT

CHITOSAN

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.

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Proper name(s)

Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose (Martindale 2010)

Common name(s)

Chitosan (Martindale 2010)

Source material(s)

- ▶ Chitin from clam (exoskeleton) (Dutta et al. 2004)
- ▶ Chitin from crab (exoskeleton) (EBSCO 2012; Martindale 2010; Dutta et al. 2004)
- ▶ Chitin from krill (exoskeleton) (Dutta et al. 2004)
- ▶ Chitin from oyster (exoskeleton) (Dutta et al. 2004)
- ▶ Chitin from shrimp (exoskeleton) (EBSCO 2012; Martindale 2010; Dutta et al. 2004)

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

- ▶ Helps lower blood total (and LDL) 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 (Willers et al. 2012; Jull et al. 2008; Mhurchu et al. 2005).

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

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

1– 6 g per day, in 2 or 3 divided doses (Mhurchu et al. 2004; Bokura and Kobayashi 2003; Tai et al. 2000).

Directions for use

- ▶ Take with meals (Bokura and Kobayashi 2003).
- ▶ Take two hours before or after taking other medications or natural health products since the absorption of these products may be delayed (EBSCO 2012).

Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

- ▶ If you are pregnant or breastfeeding, consult a healthcare practitioner prior to use (EBSCO 2012).
- ▶ If you are taking blood thinners, consult a health care practitioner prior to use (Pittler et al. 1999).

Contraindication(s)

If you have an allergy to seafood, do not use this product.

Known adverse reaction(s)

May cause abdominal pain, bloating, constipation, indigestion and/or diarrhea (Mhurchu et al. 2004; Pittler et al. 1999).

Non-medicinal ingredients

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

Note

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

References cited

Bokura H, Kobayashi S. Chitosan decreases total cholesterol in women: a randomized, double-blind, placebo-controlled trial. *European Journal of Clinical Nutrition* 2003;57(5):721-5.

Dutta PK, Dutta J, Tripathi VS. Chitin and chitosan: Chemistry, properties and applications. *Journal of Scientific & Industrial Research* 2004;63:20-31.

EBSCO 2012: EBSCO Complementary and Alternative Medicine (CAM) Review Board. Herbs and Supplements. Chitosan. [Internet]. 2011 EBSCO Publishing. [Last reviewed 2012 July; Accessed 2013 April 23]. Available from: <http://therapy.epnet.com/nat/GetContent.asp?siteid=EBSCO&chunkiid=21656>

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 1924/2006; EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), European Food Safety Authority (EFSA), Parma, Italy. [Accessed 2013 April 15].

Available from: <http://www.efsa.europa.eu/en/efsajournal/doc/2214.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.

Martindale 2010: Sweetman SC (ed), Martindale: The Complete Drug Reference. [Internet] London (GB): Pharmaceutical Press; Copyright 1933-2010. [Accessed 2013 August 12]. Available from: <http://www.medicinescomplete.com>

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: 1149-56.

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):379-81.

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):1703-4.

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 LDL-cholesterol levels in diabetic subjects by feeding bread containing chitosan. *Journal of Medicinal Food* 2003;6(4):397-9.

ChemId Advanced. Full record Poliglusam RN: 9012-76-4. [Internet]. United States National Library of Medicine. 2012 [Accessed 2013 April 23]. Available from: http://chem.sis.nlm.nih.gov/chemidplus/ProxyServlet?objectHandle=DBMaint&actionHandle=default&nextPage=jsp/chemidheavy/ResultScreen.jsp&ROW_NUM=0&TXTSUPERLISTID=0009012764



European Bioinformatics Institute. Chitosan (CHEBI: 16261). [Internet] European Molecular Biology Laboratory. 2012. [Accessed 2013 April 23]. Available from: <http://www.ebi.ac.uk/chebi/searchFreeText.do?searchString=9012-76-4>

Kaats GR, Michalek JE, Preuss HG. Evaluating efficacy of a chitosan product using a double-blinded, placebo-controlled protocol. *Journal of the American College of Nutrition* 2006;25:389-94.

Maezaki Y, Tsuji K, Nakagawa Y, Kawai Y, Akimoto M. Hypocholesterolemic effect of chitosan in adult males. *Bioscience, Biotechnology, and Biochemistry* 1993;57(9):1439-44.

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;59:741-46.

Natural Standard. Chitosan (Deacetylated chitin biopolymer). Natural Standard Professional monograph. [Internet] Natural Standard Inc. 2012 [Accessed 2013 April 23]. Available from <http://www.naturalstandard.com/databases/herbssupplements/chitosan.asp>

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):357-61.

Ylitalo R, Lehtinen S, Wuolijoki E, Ylitalo P, Lehtimäki 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;8:1962-87.