

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 statements are synonymous. Either term or statement may be selected by the applicant.

Date December 18, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Common name(s)	Organism group(s)	Part(s)
Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose	<ul style="list-style-type: none"> ▶ Chitosan ▶ Poliglusam ▶ Poly-D-glucosamine ▶ Polyglucosamine 	Chitin	<ul style="list-style-type: none"> ▶ Clam ▶ Crab ▶ Krill ▶ Oyster ▶ Shrimp 	Exoskeleton

References: Proper name: Martindale 2010; Common names: Martindale 2010; Source materials: EBSCO 2018, Martindale 2010, 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



Use(s) or Purpose(s)

- ▶ 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).

The following combined use(s) or purpose(s) is/are also acceptable:

Helps lower blood total (and LDL) cholesterol and maintain healthy cholesterol levels (EFSA 2011; Mhurchu et al. 2004; Bokura and Kobayashi 2003; Tai et al. 2000).

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 two hours before or after taking other medications or natural health products since the absorption of these products may be delayed (EBSCO 2018).

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 pregnant or breastfeeding (EBSCO 2018).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (Pittler et al. 1999).

Contraindication(s)

Do not use this product if you have an allergy to seafood.

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 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 (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%.

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