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.

Date

September 27, 2013

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


EFSA 2011: European Food Safety Authority. SCIENTIFIC OPINION: Scientific Opinion on

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.


References reviewed


