

Glucomannan

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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 July 26, 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)

Glucomannan Glucomannan Amorphophallus bulbifer Amorphophallus konjac Amorphophallus muelleri Tuber

References: Proper name: NIH 2023, RSC 2023; Common names: NIH 2023, Chua et al. 2010, RSC 2023; Source information: USDA 2023, RSC 2023. 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. The acceptable dosage forms are limited to the oral capsule and powder dosage forms listed in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s) Helps to lower cholesterol levels (by reducing cholesterol absorption from the gastrointestinal tract) (EFSA 2009; Sood et al. 2008; Martino et al. 2005; Chen et al. 2003; Arvill and Bodin 1995; Walsh et al. 1984). (Used in Herbal Medicine as a) bulk-forming laxative (Chua et al. 2010; Chen et al. 2008; Chen et al. 2006; González Canga et al. 2004; Loening-Baucke et al. 2004). (Used in Herbal Medicine to) promote(s) bowel movements (by increasing bulk volume and water content) (Chua et al. 2010; Chen et al. 2008; Chen et al. 2006; González Canga et al. 2004; Loening-Baucke et al. 2004). (Used in Herbal Medicine to) provide(s) gentle relief of constipation and/or irregularity (Chua et al. 2010; Chen et al. 2008; Chen et al. 2006; González Canga et al. 2004; Loening-Baucke et al. 2004). Note: The above uses can be combined on the product label if from the same system of medicine (e.g. Used in Herbal Medicine as a bulk-forming laxative for gentle relief of constipation and/or irregularity). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Lowering of cholesterol 1 - 1.5 grams of glucomannan, 3 times per day (EFSA 2009; Martino et al. 2005; Chen et al. 2003; Arvill and Bodin 1995; Walsh et al. 1984) Laxative; Promotion of bowel movement; Constipation relief 0.5 - 5 grams of glucomannan, 3 times per day (Chen et al. 2008; Chen et al. 2006; González Canga et al. 2004; Loening-Baucke et al. 2004) Direction(s) for use All products For each dose, drink at least 250 ml of liquid (FDA 2023, Martino et al. 2005, Chen et al. 2003, Arvill and Bodin 1995, Walsh et al. 1984). Maintain adequate fluid intake (FDA 2023; EMA 2013). Take a few hours before or after taking other medications or health products (Sweetman 2007; Keithley and Swanson 2005). Taking this product with insufficient liquid may result in choking, or blockage/obstruction of the throat, esophagus or intestine (FDA 2023; Sweetman 2007; Vanderbeek et al. 2007; Henry et al. 1986). For powder dosage forms Mix well with liquid and drink immediately. Lowering of cholesterol Take 0.5-1 hour before meals (Chen et al. 2003; Arvill and Bodin 1995; Walsh et al. 1984). Laxative; Promotion of bowel movement; Constipation relief Effects observed 12-24 hours after first dose, but may take 2-3 days (Berardi et al. 2002). Optional Take during the day (not immediately prior to bedtime) (Sweetman 2007). Optional (for products with a dosage range) Minimum daily dose may be increased, up to the maximum daily dose, until desired effect is obtained. Duration(s) of use Cholesterol-lowering products Ask a healthcare practitioner/health care provider/health care professional/doctor/physician for use beyond 8 weeks (Martino et al. 2005; Walsh et al. 1984). Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician immediately if you experience chest pain, vomiting, or difficulty swallowing or breathing after taking this product (FDA 2023). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes or a lazy bowel (UpToDate 2023; EMA 2013; Chen et al. 2003; Vuksan et al. 2001). Laxative; Promotion of bowel movement; Constipation relief Ask a health care practitioner/health care provider/health care

professional/doctor/physician if symptoms worsen or if laxative effect does not occur within 7 days (Pray 2006; Repchinsky 2002). Contraindication(s) All products Do not use if you have difficulty swallowing (FDA 2023; Sweetman 2007; Vanderbeek et al. 2007; Henry et al. 1986). Do not use if you have fever or any undiagnosed gastrointestinal trouble (EMA 2013; Pray 2006; Berardi et al. 2002). Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occurs (EMA 2013). When using this product you may experience temporary gas and bloating (Sood et al. 2008). 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 Arvill A, Bodin L. 1995. Effect of short-term ingestion of konjac glucomannan on serum cholesterol in healthy men. *American Journal of Clinical Nutrition* 61(3):585-589. Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. 2002. *Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care*, 13th edition. Washington (DC): American Pharmaceutical Association. Chen HL, Cheng HC, Wu WT, Liu YJ, Liu SY. 2008. 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Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-community-herbal-monograph-plantago-afra-l-et-plantago-indica-l-semen_en.pdf FDA 2023: United States Food and Drug Administration. Specific Labeling Requirements for Specific Drug Products. Code of Federal Regulations Title 21, Volume 4 (21CFR201.319). Rockville (MD): United States Department of Health and Human Services, U.S. Food and Drug Administration. [Accessed 2023 December 31]. Available from: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=201.319> González Canga A, Fernández Martínez N, Sahagún AM, García Vieitez JJ, Díez Liébana MJ, Calle Pardo AP, Castro Robles LJ, Sierra Vega M. 2004. Glucomanano: propiedades y aplicaciones terapéuticas [Glucomannan: properties and therapeutic applications] *Nutrición Hospitalaria* 19(1):45-50. Henry DA, Mitchell AS, Aylward J. 1986. Glucomannan and risk of esophageal obstruction. *British Medical Journal* 292:591-592. 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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. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

DOSAGE FORM(S)

The acceptable dosage forms are limited to the oral capsule and powder dosage forms listed 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 immediately if you experience chest pain, vomiting, or difficulty swallowing or breathing after taking this product (FDA 2023). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes or a lazy bowel (UpToDate 2023; EMA 2013; Chen et al. 2003; Vuksan et al. 2001). Laxative; Promotion of bowel movement; Constipation relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or if laxative effect does not occur within 7 days (Pray 2006; Repchinsky 2002). Contraindication(s) All products Do not use if you have difficulty swallowing (FDA 2023; Sweetman 2007; Vanderbeek et al. 2007; Henry et al. 1986). Do not use if you have fever or any undiagnosed gastrointestinal trouble (EMA 2013; Pray 2006; Berardi et al. 2002). Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occurs (EMA 2013). When using this product you may experience temporary gas and bloating (Sood et al. 2008).

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.

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. EXAMPLE OF

PRODUCT FACTS:

REFERENCES

Route of administration Oral

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Glucomannan	Glucomannan	Amorphophallus bulbiferAmorphophallus konjacAmorphophallus muelleri	5