

# Inulin

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Inulin (PDF Version - 92 K) 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 September 27, 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) Inulin Inulin Cichorium intybus Root Helianthus tuberosus Tuber References: Proper name: CFIA 2016; IOM 2005; Common name: CFIA 2016; IOM 2005; Source information: USDA 2024; CFIA 2016; IOM 2005; Gardner and McGuffin 2013. 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) Source of fiber for the maintenance of good health (FCC 2023; CFIA 2016; IOM 2005). Helps support and maintain a healthy digestive system (FCC 2023; CFIA 2016; IOM 2005). Helps stimulate the growth of healthy bacteria (such as bifidobacteria) in the intestine/gut (Marteau et al. 2011; Roberfroid 2007a; Menne et al. 2000; Gibson et al. 1995). Prebiotic (Marteau et al. 2011; Ramnani 2010; Roberfroid 2007a,b; Menne et al. 2000; Gibson et al. 1995). Helps provide gentle relief of constipation and/or irregularity (Marteau et al. 2011; IOM 2005; Kleessen et al. 1997). Notes: The above uses can be combined on the product label (e.g. Prebiotic which helps stimulate the growth of healthy bacteria (such as bifidobacteria) in the intestine/gut). The terms 'Helps' or 'Helps to' can be used interchangeably on the label. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) 1 All products 2-15 grams of Inulin, per day (Kolida and Gibson 2007; IOM 2005; Menne et al. 2000; Coussement 1999). 1 Note: Inulin preparations containing 90% or more inulin are acceptable, provided the quantity of inulin listed on the PLA form and label represents the inulin content only. Direction(s) for use Products providing 5 g or more of Inulin, per dose Take with at least 250 ml of liquid (Pray 2006). Take a few hours before or after taking other medications or health products (Pray 2006). For powder dosage forms Mix well with liquid and drink immediately (Pray 2006). Optional Take during the day (not immediately prior to bedtime) (Sweetman 2007). Duration(s) of use No statement required. Risk information Caution(s) and warning(s) Products for constipation/irregularity 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). Products providing 5 g or more of Inulin, per dose Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Pray 2006). Contraindication(s) Products for constipation/irregularity Do not use if you have fever or any undiagnosed gastrointestinal trouble (HC 2009). Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occurs (Brinker 2010; Hendler and Rorvik 2008; Franck et al. 2005; Gay-Crosier et al. 2000). Products providing 5 g or more of Inulin, per day When using this product you may experience temporary gas and bloating (Marteau et al. 2011; Kolida and Gibson 2007; Menne et al. 2000; Coussement 1999; Kleessen et al. 1997). 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 Brinker F. 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Pourghassem GB, Dehghan P, Aliasgharzadeh A, Asghari J-AM. Effects of high performance inulin supplementation on glycemic control and antioxidant status in women with type 2 diabetes. *Diabetes Metabolism Journal* 2013;37(2):140-148. Rao AV. Dose-Response effects of inulin and oligofructose on intestinal bifidogenesis effects. *Journal of Nutrition* 1999;129:1442S-1445S. Roberfroid MB, Van Loo JAE, Gibson GR. The bifidogenic nature of chicory inulin and its hydrolysis products *Journal of Nutrition* 1998;128:11-19. Szajewska H, Wizman Z, Abu-Zekry M, Kekez A, Braegger C, Kolacek S, Micetic-Turk D, Ruszczynski M, Vukavic T. Inulin and fructo-oligosaccharides for the prevention of antibiotic-associated diarrhea in children: report by the ESPGHAN working group on probiotics and prebiotics. *Journal of Pediatric Gastroenterology and Nutrition* 2012;54(6):828-829. Van Dokkum W, Wezendonk B, Sriksumar TS, van den Heuvel EGHM. Effect of nondigestible oligosaccharides on large-bowel functions, blood lipid concentrations and glucose absorption in young healthy male subjects. *European Journal of Clinical Nutrition* 1999;53(1):1-7. Yap WKW, Mohamed S, Jamal MH, Meyer D, Manap YA. Changes in infant faecal characteristics and microbiota by inulin supplementation. *Journal of Clinical Biochemistry Nutrition* 2008;43:159-166. WHO 1999: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 1. Geneva (CH): World Health Organization; 1999. 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. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

## **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) Products for constipation/irregularity 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). Products providing 5 g or more of Inulin, per dose Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Pray 2006). Contraindication(s) Products for constipation/irregularity Do not use if you have fever or any undiagnosed gastrointestinal trouble (HC 2009). Known adverse reaction(s) All products Stop use if hypersensitivity/allergy occurs (Brinker 2010; Hendler and Rorvik 2008; Franck et al. 2005; Gay-Crosier et al. 2000). Products providing 5 g or more of Inulin, per day When using this product you may experience temporary gas and bloating (Marteau et al. 2011; Kolida and Gibson 2007; Menne et al. 2000; Coussement 1999; Klessen et al. 1997).

## **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)		
Inulin	Inulin	Cichorium intybus	Root
Helianthus tuberosus	Tuber		