

NATURAL HEALTH PRODUCT

INULIN

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

October 29, 2021

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		Preparation(s)
		Source material(s)	Part(s)	
Inulin	Inulin	<i>Cichorium intybus</i>	Root	Isolate
		<i>Helianthus tuberosus</i>	Tuber	

References: Proper name: CFIA 2016, IOM 2005; Common name: CFIA 2016, IOM 2005; Source information: USDA 2019a,b, CFIA 2016, IOM 2005, McGuffin et al. 2000.

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 (CFIA 2016; FCC 8 2012; IOM 2005).
- ▶ Helps support and maintain a healthy digestive system (CFIA 2016; FCC 8 2012; 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; 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).

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

Prebiotic which helps stimulate the growth of healthy bacteria (such as bifidobacteria) in the intestine/gut (Marteau et al. 2011; Roberfroid 2007a,b; Menne et al. 2000; Gibson et al. 1995).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Source of fiber, healthy digestive system, constipation/irregularity

2 - 15 grams of Inulin, per day (Kolida and Gibson 2007; IOM 2005; Menne et al. 2000; Coussement 1999).

Prebiotic, healthy bacteria

5 - 15 grams of Inulin, per day (Kolida and Gibson 2007; Menne et al. 2000; Coussement 1999).

Direction(s) for use

Products providing 5 g or more of Inulin, per dose

Powder

- ▶ Mix well with at least 240 milliliters of liquid (e.g. water, milk, fruit juice or similar aqueous beverage). Stir briskly and drink immediately (Pray 2006).
- ▶ Take 2 hours before or after taking other medications or natural health products (Pray 2006).
- ▶ *Optional:* Take during the day (not immediately prior to bedtime) (Sweetman 2007).

Other dosage forms

- ▶ Take with at least 240 milliliters of liquid (e.g. water, milk, fruit juice or similar aqueous



beverage) (Pray 2006).

- ▶ Take 2 hours before or after taking other medications or natural health products (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

- ▶ Consult 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).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have symptoms such as abdominal pain, nausea, vomiting or fever (as these could be signs of other serious conditions) (Pray 2006).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are experiencing a sudden change in bowel habits that has persisted for more than 2 weeks, undiagnosed rectal bleeding, or have failed to defecate following the use of a laxative product (Pray 2006).

Products providing 5 g or more of Inulin, per dose

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have diabetes (Pray 2006).

Contraindication(s)

No statement required.

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

May cause temporary gas and/or 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

Store in a well-closed container at room temperature (USP 35 2012).

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.

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