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

Date

October 4, 2013

Proper name(s)

Inulin (CFIA 2012; IOM 2005)

Common name(s)

Inulin (CFIA 2012; IOM 2005)

Source material(s)

- *Helianthus tuberosus* L. - tuber (Jerusalem artichoke) (CFIA 2012; USDA 2010)

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

- Source of fiber for the maintenance of good health (CFIA 2012; FCC 8; IOM 2005).
- Helps support and maintain a healthy digestive system (CFIA 2012; FCC 8; 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).

**Dose(s)**

**Subpopulation(s)**

Adults (≥ 18 years)

**Quantity(ies)**

*Source of fiber, healthy digestive system, constipation/irregularity*

2-15 g, per day (Kolida and Gibson 2007; IOM 2005; Menne et al. 2000; Cousssem 1999).

*Prebiotic, healthy bacteria*

5-15 g, per day (Kolida and Gibson 2007; Menne et al. 2000; Cousssem 1999).

**Directions for use**

*Products providing ≥ 5 g inulin per dose*

- Take with 250 ml of water (Pray 2006).
- Take two hours before or after taking other medications or natural health products since the absorption of these products may be delayed (Pray 2006).

**Duration of use**

No statement required.

**Risk information**

Statement(s) to the effect of

**Caution(s) and warning(s)**
Products providing ≥ 5 g inulin per dose

If you have diabetes, consult a health care practitioner prior to use (Pray 2006).

Products for constipation/irregularity

- If symptoms worsen or if laxative effect does not occur within seven days, consult a health care practitioner (Pray 2006).
- If you are taking medications which inhibit peristaltic movement, consult a health care practitioner prior to use (e.g. opioids, loperamide) (Pray 2006).
- If you have symptoms such as abdominal pain, nausea, vomiting or fever, consult a health care practitioner prior to use (Pray 2006).
- 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, consult a health care practitioner prior to use (Pray 2006).

Contraindication(s)

No statement required.

Known adverse reaction(s)

All products

Hypersensitivity has been known to occur (Brinker 2010; Hendler and Rorvik 2008; Franck et al. 2005; Gay-Crosier et al. 2000).

Products providing ≥ 5 g per day

May cause mild gastro-intestinal discomfort (such as gas, bloating, cramps) (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 NHPD Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Statement(s) to the effect of

Store in well-closed containers at room temperature (USP 35).

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). In addition, the medicinal ingredient may comply with the specifications outlined in the Inulin monograph published in the United States Pharmacopeia (USP 35).

References cited


Menne E, Guggenbuhl, Roberfroid M. Fn-type chicory inulin hydrolysate has a prebiotic effect in humans. Journal of Nutrition 2000;130:1197-1199.


References reviewed


