

## 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)

- ▶ *Cichorium intybus* L. - root (Chicory) (CFIA 2012; USDA 2012; IOM 2005; McGuffin et al. 2000)
- ▶ *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 ( $\geq 18$  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; Coussement 1999).

*Prebiotic, healthy bacteria*

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

**Directions for use**

*Products providing  $\geq 5$  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  $\geq 5$  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  $\geq 5$  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).

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