

NATURAL HEALTH PRODUCT

INDOLE-3-CARBINOL

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 December 8, 2015

Proper name(s)

3-Hydroxymethylindole (NIH 2012)

Common name(s)

Indole-3-carbinol (NIH 2012)

Source material(s)

- ▶ *Brassica oleracea* var. *botrytis* (Cauliflower) – whole plant
- ▶ *Brassica oleracea* var. *capitata* (Cabbage) – whole plant
- ▶ *Brassica oleracea* var. *gemmifera* (Brussels Sprouts) – whole plant
- ▶ *Brassica oleracea* var. *italica* (Broccoli, Heading Broccoli, Sprouting Broccoli) – whole plant (Jongen 1996; Kwon *et al.* 1994; Bradfield and Bjeldanes 1991)
- ▶ Synthetic (Komiyama *et al.* 1995)

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 antioxidants/Provides antioxidants (Fowke *et al.* 2006; Reed *et al.* 2005; Herraiz *et al.* 2004).
- ▶ Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effects of/the oxidative damage caused by/cell damage caused by) free radicals (Fowke *et al.* 2006; Reed *et al.* 2005; Herraiz *et al.* 2004).
- ▶ Helps to support/promote healthy estrogen metabolism/balance (Reed *et al.* 2005; Bell *et al.* 2000; Wong *et al.* 1997; Bradlow *et al.* 1994).

Dose(s) Statement(s) to the effect of

Subpopulation

Adults (≥ 18 years)

Quantiti(es)

Antioxidant

Up to 400 mg indole-3-carbinol per day (Laidlaw *et al.* 2010; Naik *et al.* 2006; Reed *et al.* 2005; McAlindon *et al.* 2001; Bell *et al.* 2000; Wong *et al.* 1997; Bradlow *et al.* 1994).

Healthy Estrogen Metabolism

200 – 400 mg indole-3-carbinol per day (Laidlaw *et al.* 2010; Naik *et al.* 2006; Reed *et al.* 2005; McAlindon *et al.* 2001; Bell *et al.* 2000; Wong *et al.* 1997; Bradlow *et al.* 1994).

Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

Products providing ≥ 20 mg indole-3-carbinol per day



- ▶ If you are taking medications or natural health products, consult a health care practitioner prior to use (Brinker 2010; Linus Pauling Institute 2008; Reed *et al.* 2005; Bradlow *et al.* 1994).
- ▶ If you are attempting to conceive, consult a health care practitioner prior to use (Bennetts *et al.* 2008; Michnovicz *et al.* 1997).
- ▶ If you have a liver disorder or symptoms of low estrogen (such as joint pain, mood changes, changes in libido, hot flashes, night sweats, vaginal dryness or irregular menstruations), consult a health care practitioner prior to use (Reed *et al.* 2005; Dalessandri *et al.* 2004; Bell *et al.* 2000; Michnovicz *et al.* 1997; Wong *et al.* 1997; Bradlow *et al.* 1994).
- ▶ If you develop liver-related symptoms (e.g. yellowing of the eyes and/or skin, dark urine, abdominal pain, jaundice) or symptoms of low estrogen, discontinue use and consult a health care practitioner (Reed *et al.* 2005; Dalessandri *et al.* 2004; Bell *et al.* 2000; Michnovicz *et al.* 1997; Wong *et al.* 1997; Bradlow *et al.* 1994).

Note: Specific symptoms of low estrogen are not always applicable and should be chosen based on intended subpopulation. As an example, for a male subpopulation, symptoms, such as hot flashes, night sweats, vaginal dryness and irregular menstruations, are not applicable.

Products making healthy estrogen balance/metabolism claim

To exclude the diagnosis of a serious cause of hormonal imbalance, consult a health care practitioner prior to use (UpToDate 2014).

Contraindication(s)

All products

If you are pregnant or breastfeeding, do not use this product (Reed *et al.* 2006, Michnovicz *et al.* 1997).

Known adverse reaction(s)

No statement required.

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

Keep in a cool, dry place, protected from light (Zeligs 2001).

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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