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. *gemmafera* (Brussels Sprouts) – whole plant
► 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)**

- 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)**

- **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**

**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 NHPIID.

References cited


References reviewed


Rogan EG. The natural chemopreventive compound indole-3-carbinol: state of the science. In Vivo 2006;20:221–228.


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