

## 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

February 24, 2023

#### 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 ingredient(s)	Source material(s)	Part(s)	
3-Hydroxymethyl indole	Indole-3-carbinol	N/A	<ul style="list-style-type: none"> <li>▶ <i>Brassica oleracea</i> var. <i>botrytis</i></li> <li>▶ <i>Brassica oleracea</i> var. <i>capitata</i></li> <li>▶ <i>Brassica oleracea</i> var. <i>gemmifera</i></li> <li>▶ <i>Brassica oleracea</i> var. <i>italica</i></li> </ul>	Whole plant	Isolate
		Indole-3-carbinol	N/A	N/A	

References: Proper name: NIH 2019; Common name: NIH 2019; Source information: Jongen 1996, Komiyama et al. 1995, Kwon et al. 1994, Bradfield and Bjeldanes 1991.

#### 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/Provides (an) antioxidant(s) (Fowke et al. 2006; Reed et al. 2005; Herraiz et al. 2004).
- ▶ Source of/Provides (an) antioxidant(s) that help(s) 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).

**Note:** If Indole-3-carbinol is combined with another medicinal ingredient with antioxidant properties at Class II and III, there is an option to use the antioxidant statements in plural. The singular should be used when the product only contains one medicinal ingredient associated with this claim.

## Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

#### *Antioxidant*

Not to exceed 400 milligrams of 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 milligrams of 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).

### Direction(s) for use

No statement required.

## Duration(s) of use

No statement required.

## Risk information

### Caution(s) and warning(s)

#### *Products making a healthy estrogen balance/metabolism claim*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use to exclude the diagnosis of a serious cause of hormonal imbalance (UpToDate 2019).

#### *Products providing 20 mg or more of Indole-3-carbinol, per day*

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking medications or natural health products (Linus Pauling Institute 2017; Brinker 2010; Reed et al. 2005; Bradlow et al. 1994).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are attempting to conceive (Bennetts et al. 2008; Michnovicz et al. 1997).
- ▶ Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician 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 (Reed et al. 2005; Dalessandri et al. 2004; Bell et al. 2000; Michnovicz et al. 1997; Wong et al. 1997; Bradlow et al. 1994).

#### *Products providing 20 mg or more of Indole-3-carbinol, per day*

#### *All subpopulations or Female subpopulation only*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use 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 (Reed et al. 2005; Dalessandri et al. 2004; Bell et al. 2000; Michnovicz et al. 1997; Wong et al. 1997; Bradlow et al. 1994).

#### *Male subpopulation only*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a liver disorder or symptoms of low estrogen such as joint pain, mood changes or changes in libido (Reed et al. 2005; Dalessandri et al. 2004; Bell et al. 2000; Michnovicz et al. 1997; Wong et al. 1997; Bradlow et al. 1994).



## **Contraindication(s)**

*All products*

Do not use this product if you are pregnant or breastfeeding (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 (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

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