Indole-3-carbinol

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Monograph: Indole-3-Carbinol Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 133 KB) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA s) 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 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 on the label. Restrictions when this monograph is combined with other monographs (Class II and III applications): Indole-3-carbinol cannot be combined with other monographed ingredients with estrogenic or anti-estrogenic effects as a Class II application (e.g., Soybean Extracts and Isolates, DIM, Red clover isoflavone extract, Tribulus terrestris, Brassica oleracea varieties (cruciferous vegetables), Dong quai - Angelica sinensis). Theses products may be submitted as a Class III application. Date June 27, 2025 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 Source ingredient(s) Source material(s) Part(s) Preparation(s) 3-Hydroxymethylindole Indole-3-carbinol N/A Brassica oleracea var. botrytis Brassica oleracea var. capitata Brassica oleracea var. gemmifera Brassica oleracea var. italica Whole plant Isolate Indole-3-carbinol N/A N/A Synthetic References: Proper name: NIH 2024; Common name: NIH 2024; 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 (an) antioxidant(s)/Provides (an) antioxidant(s) (Fowke et al. 2006; Reed et al. 2005; Herraiz et al. 2004). Source of (an) antioxidant(s)/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect 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 chemical substance as the 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 Ask а health care practitioner/health care provider/health professional/doctor/physician before use to exclude the diagnosis of a serious cause of hormonal imbalance (UpToDate 2024). Products providing 20 mg or more of Indole-3-carbinol, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking medications or natural health products (Linus Pauling Institute 2017; Brinker 2010; Reed et al. 2005; Bradlow et al. 1994). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are attempting to conceive (Bennetts et al. 2008; Michnovicz et al. 1997). Stop use and ask 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 Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 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 and Non-prescription Health Products Directorate Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage Conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations. 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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carbinol&queryBean.stars=3&queryBean.stars=-1 Dashwood RH. 1998. Indole-3-carbinol: anticarcinogen or tumor promoter in brassica vegetables? Chemico-Biological Interactions 110(1-2):1-5. [Abstract only] Higdon JV, Delage B, Williams DE, Dashwood RH. Cruciferous Vegetables and Human Cancer Risk: Epidemiologic Evidence and Mechanistic Basis. Pharmacological Research 2007; 55(3):224-236. iHerb Natural Products. 2024. [Accessed: 2024 June 25]. Available from: http://www.iherb.com/Indole-3-Carbinol Kim YS, Milner JA. Targets for indole-3-carbinol in cancer prevention. Journal of Nutritional Biochemistry 2005;16:65-73. Michnovicz JJ. Increased estrogen 2-hydroxylation in obese women using oral indole-3-carbinol. International Journal of Obesity and Related Metabolic Disorders 1998;22:227-229. [Abstract only] Minich DM, Bland JS. A Review of the Clinical Efficacy and Safety of Cruciferous Vegetable Phytochemicals Nutrition Reviews 2007;65(6):259-267. [Abstract only] NCBI 2024: National Center for Biotechnology Information. [Accessed: 2024 June 25]. Available from: https://pubchem.ncbi.nlm.nih.gov/compound/3712 Rogan EG. The natural chemopreventive compound indole-3-carbinol: state of the science. In Vivo 2006;20:221-228. Rosen CA, Bryson PC. Indole-3-carbinol for recurrent respiratory papillomatosis: long-term results. Journal of Voice 2004;18:248-253. Rosen CA, Woodson GE, Thompson JW, Hengesteg AP, Bradlow HL. Preliminary results of the use of indole-3-carbinol for recurrent respiratory papillomatosis. Otolaryngology - Head and Neck Surgery 1998;118(6):810-815. Sarkar FH, Li Y. Indole-3-carbinol and prostate cancer. Journal of Nutrition 2004;134:3493S- 3498S. Verhoeven DT, Verhagen H, Goldbohm RA, van den Brandt PA, van Poppe. G. A review of mechanisms underlying anticarcinogenicity by brassica vegetables. Chemico-Biological Interactions. 1997;103(2):79-129. [Abstract only] Yuan Gao-feng, Bo Sun, Jing Yuan, and Qiao-mei Wang. Effects of different cooking methods on health-promoting compounds of broccoli. Journal of Zhejiang University Science B 2009; 10(8):580-588. [Abstract only] Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

Must be chosen from the current Natural and Non-prescription Health Products DirectorateNatural Health Products Ingredients Database(NHPID) and must meet the limitations outlined in the database. Storage Conditions Must be established in accordance with the requirements described in theNatural Health Products Regulations.

DOSAGE FORM(S)

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.

RISK INFORMATION

Caution(s) and warning(s) Products making a healthy estrogen balance/metabolism claim Ask a health care practitioner/health care provider/health care professional/doctor/physician before use to exclude the diagnosis of a serious cause of hormonal imbalance (UpToDate 2024). Products providing 20 mg or more of Indole-3-carbinol, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking medications or natural health products (Linus Pauling

Institute 2017; Brinker 2010; Reed et al. 2005; Bradlow et al. 1994). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are attempting to conceive (Bennetts et al. 2008; Michnovicz et al. 1997). Stop use and ask 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 Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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 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 and Non-prescription Health Products DirectorateNatural Health Products Ingredients Database(NHPID) and must meet the limitations outlined in the database. Storage Conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Oral

me(s)	Common name(s)	Source information		
edient(s)	Source material(s)	Part(s)	Preparation(s)	
ethylindole	Indole-3-carbinol	N/A	Brassica oleraceavar.botrytisBrassica olera	c elâWhaorlecapphataat taBras
binol	N/A	N/A	Synthetic	