NATURAL HEALTH PRODUCT

3,3’-DIINDOLYLMETHANE (DIM)

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)

- 3,3’-Diindolylmethane (NIH 2014)
- 3,3’-Methylenebis-1H-indole (NIH 2014)

Common name(s)

- 3,3’-Diindolylmethane (NIH 2014)
- DIM (NIH 2014)

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 (Pradhan *et al.* 2005)

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).
- Helps reduce the severity and duration of symptoms associated with recurrent breast pain (cyclical mastalgia) (Reed et al. 2005; Zeligs et al. 2005).

Dose(s)

Statement(s) to the effect of

Subpopulation

Adults (≥ 18 years)

Quantities

Antioxidant

Up to 200 mg DIM per day (Laidlaw et al. 2010; Reed et al. 2008; 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

60 – 200 mg DIM per day (Laidlaw et al. 2010; Reed et al. 2008; Naik et al. 2006; Reed et al. 2005; Zeligs et al. 2005; McAlindon et al. 2001; Bell et al. 2000; Wong et al. 1997; Bradlow et al. 1994).

Recurrent breast pain

60 – 200 mg DIM per day (Laidlaw et al. 2010; Reed et al. 2008; Naik et al. 2006; Reed et al. 2005; Zeligs 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 $\geq 6$ mg DIM 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 healthcare 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).

Recurrent breast pain

If symptoms persist or worsen, consult a health care practitioner.

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.

References cited


Brinker F. Final Updates and Additions for Herb Contraindications and Drug Interactions, 3rd edition. [Internet]. Sandy (OR): Eclectic Medical Publications. [Last update 2010 July 13;


Reed GA, Arneson DW, Putnam WC, Smith HJ, Gray JC, Sullivan DK, Mayo MS, Crowell JA,


References reviewed


ChEBI 2012: Chemical Entities of Biological Interest. [Internet]. [Accessed: 2012 March 12]. Available from: http://www.ebi.ac.uk/chebi/advancedSearchFT.do?searchString=indole-3-carbinol&queryBean.stars=3&queryBean.stars=-1


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


