

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 January 26, 2024

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)
<ul style="list-style-type: none"> • 3,3'-Diindolylmethane • 3,3'-Methylenebis-1H-indole 	<ul style="list-style-type: none"> • 3,3'-Diindolylmethane • DIM 	N/A	<ul style="list-style-type: none"> • <i>Brassica oleracea</i> var. <i>botrytis</i> • <i>Brassica oleracea</i> var. <i>capitata</i> • <i>Brassica oleracea</i> var. <i>gemmifera</i> • <i>Brassica oleracea</i> var. <i>italica</i> 	Whole plant	Isolate
		3,3'-Diindolylmethane	N/A	N/A	Synthetic

References: Proper names: NIH 2023; Common names: NIH 2023; Source information: Pradhan et al. 2005, Jongen 1996, 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 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).

Note: If 3,3'-Diindolylmethane (DIM) is combined with other medicinal ingredients with antioxidant properties, there is an option to use the claim in plural. The singular should be used when the product only contains one chemical substance (e.g. DIM) as the medicinal ingredient associated with the claim.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Antioxidant

Not to exceed 200 milligrams of 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; Recurrent Breast Pain

60 – 200 milligrams of 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).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Products making 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 2023).

Recurrent breast pain

Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

Products providing 6 milligrams or more of DIM, 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 (Brinker 2010; Linus Pauling Institute 2008; 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 6 milligrams or more of DIM, 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 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*.

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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
<p>Medicinal ingredient in each capsule 3,3'-Diindolylmethane (DIM) (<i>Brassica oleracea</i> var. <i>botrytis</i> – whole plant) XX mg</p>
<p>Uses</p> <ul style="list-style-type: none"> • Source of an antioxidant/Provides an antioxidant • Source of an antioxidant/Provides an antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals • Helps to support/promote healthy estrogen metabolism/balance • Helps reduce the severity and duration of symptoms associated with recurrent breast pain (cyclical mastalgia)
Warnings
<p>If applicable: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame</p>
Do not use if you are pregnant or breastfeeding
<p>Ask a health care practitioner before use if: <i>Products providing 6 milligrams or more of DIM, per day</i></p> <ul style="list-style-type: none"> • you are taking medications or natural health products. • you are attempting to conceive. <p><i>All subpopulations or Female subpopulation only</i></p> <ul style="list-style-type: none"> • 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. <p><i>Male subpopulation only</i></p> <ul style="list-style-type: none"> • you have a liver disorder or symptoms of low estrogen such as joint pain, mood changes or changes in libido.
<p><i>Products making healthy estrogen balance/metabolism claim</i> Ask a health care practitioner before use to exclude the diagnosis of a serious cause of hormonal imbalance.</p>
<p><i>Recurrent breast pain</i> Ask a health care practitioner if symptoms persist or worsen.</p>
<p><i>Products providing 6 milligrams or more of DIM, per day</i> Stop use and ask a health care practitioner 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.</p>
<p>Directions Adults 18 years and older: Take X capsule(s), X times a day.</p>
<p>Other information</p> <ul style="list-style-type: none"> • Keep in a cool, dry place protected from light. <p>(Add any other storage information)</p>
<p>Non-medicinal ingredients List all NMIs</p>



Questions? Call 1-XXX-XXX-XXXX

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