

CLINICAL PROTOCOL TO SUPPORT NORMAL HORMONAL BALANCE AND A HEALTHY INFLAMMATORY RESPONSE FOR PMS*

Premenstrual syndrome (PMS) affects a significant portion of females of reproductive age. Approximately 80% to 90% of menstruating individuals report experiencing at least one PMS symptom during their life, but many may not meet the diagnostic criteria. The prevalence of diagnosed PMS is an estimated 47.8%, whereas the prevalence of premenstrual dysphoric disorder (PMDD), which is more severe, is approximately 2% to 5% of these individuals.^{1,3}

PMS symptoms begin in the luteal phase of the menstrual cycle. These symptoms resolve shortly after bleeding commences. Symptoms vary, with hundreds of potential manifestations that may fluctuate in time. The most common symptoms include mood swings, irritability, depression, anxiety, bloating, cramping, headaches, and breast tenderness. Individuals may also experience an exacerbation of existing conditions. PMS may significantly affect quality of life and impact normal daily functioning.^{1,4-6}

The etiology and pathophysiology of PMS continue to be researched. Cyclical hormonal changes may likely play a role, possibly due to the effects of estrogen and progesterone on serotonin, gamma-aminobutyric acid, and dopamine systems. Potentially, the hypothalamic-pituitary-adrenal axis is involved, along with a likely genetic component.^{1,2,7-9}

Diagnosis generally relies on symptom questionnaires and patient history. Common treatments include dietary and lifestyle changes with medication targeted at symptomatic improvement and hormonal balance.^{1,3} This clinical protocol is designed to promote normal hormonal balance and a healthy inflammatory response to support PMS.*



Diagnostic Biomarkers and Clinical Indicators of PMS

- Validated Questionnaire Screening Tools^{10,11}
 - Daily Record of Severity of Problems (DRSP)
 - Premenstrual Symptoms Screening Tool (PSST)

Therapeutic Diet and Nutritional Considerations

- Counsel patients on consuming a diet rich in fruits and vegetables, as it has been shown to reduce the occurrence and severity of PMS symptoms^{5,12,13}
- Instruct patients to reduce consumption of fast foods, highly processed foods, and foods with high sugar content, as this has been found to correlate with increased risk of PMS. Lower consumption of these foods has been found to reduce PMS symptoms^{5,13}
- Recommend a diet rich in calcium (such as those listed below), especially during the luteal phase, because low serum levels of calcium have been found to correlate with PMS symptoms^{14,15}
 - Almonds
 - Beans and lentils
 - Cheese
 - Dark leafy greens
 - Edamame
 - Sardines
 - Yogurt

Lifestyle Intervention

- Counsel patients on limiting or restricting alcohol intake, as alcohol consumption (especially heavy drinking) is associated with an increased risk of PMS⁴
- Recommend an exercise routine, since exercise (especially aerobic exercise, swimming, and yoga) has been shown to significantly reduce PMS symptoms^{6,8,9,16}
- Advise patients on smoking cessation, as smoking has a significant association with PMS severity⁵
- Instruct patients on stress relief practices, as stress has been shown to increase the risk of PMS and exacerbate its symptoms^{17,18}
- Counsel patients on sleep hygiene and provide support for sleep disorders, as sleep problems are correlated with PMS^{19,20}

This information is provided as a medical and scientific educational resource for the use of physicians and other licensed health-care practitioners ("Practitioners"). This information is intended for Practitioners to use as a basis for determining whether to recommend these products to their patients. All recommendations regarding protocols, dosing, prescribing and/or usage instructions should be tailored to the individual needs of the patient considering their medical history and concomitant therapies. This information is not intended for use by consumers.



Supplement Protocol

Primary Support:



D-Evail™ Supreme

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| Dose | 1 to 2 softgels with a meal based on testing |
| Duration | Ongoing as needed |
| Formula Highlights | D-Evail™ Supreme provides a clinically relevant serving of 5,000 IU (125 mcg) of vitamin D in a highly absorbable form alongside vitamin K1 and K2 (as MK-4), and geranylgeraniol (GG) to support bone, immune, and cardiovascular health.* Research suggests that combined supplementation of both vitamins D and K may be more supportive than either vitamin alone for both bone health and cardiovascular health.* This product uses Designs for Health's Evail™ system technology that combines quillaja extract with medium-chain triglycerides (MCT) for improved nutrient bioavailability.* |

Cal/Mag 1:1

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| Dose | 2 capsules twice daily with meals |
| Duration | Ongoing as needed |
| Formula Highlights | Cal/Mag 1:1 provides calcium and magnesium in equal amounts, with 200 mg of each mineral per serving of 2 capsules. Although the most commonly recommended dietary ratio of calcium to magnesium is 2:1, magnesium depletion has become very common in the U.S. Many components of the modern lifestyle increase magnesium loss, including stress (physical or emotional), alcohol or coffee consumption, exercise, excessive sweating, and certain medications, such as birth control pills, various antibiotics, and common diuretics. These factors cause many individuals to require compensation for extra magnesium. |

FemGuard + Balance™

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| Dose | 2 capsules twice daily with meals |
| Duration | Ongoing as needed |
| Formula Highlights | FemGuard + Balance™ supports classic herbal hormonal balancing in the form of vitex, polygonum, and black cohosh, along with diindolymethane (DIM) and chrysin for protection and support of beneficial estrogen aromatase activity. Calcium-D-glucarate promotes the proper elimination of excess estrogens. Resveratrol and epigallocatechin gallate (EGCg) from green tea are included for their antioxidant properties. Vitamins B6, B12, and folate promote proper cell differentiation. Magnesium and calcium are also included to help support bone and hormone health.* |

XanthOmega™ Krill Oil

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| Dose | 1 softgel twice daily with meals |
| Duration | Ongoing as needed |
| Formula Highlights | XanthOmega™ Krill Oil provides a generous 12 mg per serving of astaxanthin to help achieve optimum benefits from this potent carotenoid. It would take eight conventional krill softgels to equal the astaxanthin levels in just one XanthOmega™ softgel. XanthOmega™ Krill Oil has a high phospholipid content, standardized to a minimum of 40% phospholipids, mostly as phosphatidylcholine. This is considered to be a virgin krill oil, the purest form available. It contains higher phospholipid bioavailability, which enhances the absorption of astaxanthin. Many studies suggest that this exceptionally high level of astaxanthin offers a wide array of benefits, which may include powerful antioxidant properties and support for cardiovascular, skin, eye, and gastric health. Astaxanthin also assists the body with a healthy inflammatory response.* |

For a list of references cited in this document, please visit:

<https://www.designsforhealth.com/protocol-references/protocol-pms-references.pdf>

Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Health-care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities, appropriate monitoring, including liver function tests (LFT) is recommended.

For considerations regarding herb-drug and nutrient-drug interactions, please refer to reliable, evidence-based resources such as the Natural Medicine Database or Stargrove MB, Treasure J, McKee DL. *Herb, Nutrient, and Drug Interactions: Clinical Implications and Therapeutic Strategies*. St. Louis, MO: Mosby-Elsevier; 2008.

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