

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Pregnenolone/Enclomiphene Citrate

Form: Oral Capsule

Drug Class:

- Pregnenolone: Endogenous steroid precursor/neurosteroid, upstream of progesterone, DHEA, androgens, estrogens, and cortisol.
 - Enclomiphene: Selective estrogen receptor modulator (SERM) — the trans-isomer of clomiphene. Acts as an estrogen antagonist in the hypothalamus and pituitary.
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Mechanism of Action^{1,2}: Together, Pregnenolone may supply precursor material while enclomiphene may enhance pituitary drive, potentially improving overall androgen status.

Pregnenolone is intended to:

- Drive hormone production by converting into progesterone, cortisol, DHEA, testosterone, and estrogens to direct fuel the body's steroid hormone pathways.
- Activate brain signaling to enhance excitatory NMDA activity and modulate GABAA inhibition — supporting memory, alertness, and balanced mood.

Enclomiphene is intended to:

- Stimulate gonadotropins: Blocks estrogen's negative feedback at the hypothalamus/pituitary → increases GnRH → raises LH and FSH.
 - Boost testosterone production: Higher LH/FSH stimulate Leydig and Sertoli cells, increasing testicular testosterone and spermatogenesis.
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Indications Commonly Prescribed for:

- Male hypogonadism or infertility
 - Age-related hormone decline for symptoms such as fatigue, low libido, or mood changes
 - Neurocognitive / mood support
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Before Use: Let your health care provider know if you have any medication allergies before you take this compounded preparation. Let your health care provider know if you have any liver or kidney problems. Let your healthcare provider know of all supplements you are currently taking.

Contraindications:

- Known hypersensitivity to either component.
 - Hormone-sensitive conditions (caution/avoid): Given conversion to downstream sex steroids, avoid or exercise caution in active hormone-dependent cancers unless directed by a specialist.
 - Avoid in patients at high risk of thromboembolism.
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Cautions: Let your Healthcare provider know if you experience any adverse side effects.

How to Use: This compounded preparation is in the form of an oral capsule. Swallow the capsule whole with a glass of water. Do not chew or crush the capsule. If you miss a dose, take as soon as you remember, but not at the time for the next dose. Desired results may take up to several weeks.

Compounded medications are not FDA-approved and may differ in risks, benefits, and side effects from FDA-approved products. These statements have not been evaluated by the FDA and are not intended to diagnose, treat or cure any disease or condition and do not indicate any claims of safety or efficacy. Individual results may vary.

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Warnings and Precautions:

- Hormonal conversion variability: Pregnenolone metabolism is inconsistent among individuals and may lead to unpredictable hormone levels.
 - Neuropsychiatric effects: Through neurosteroid pathways (e.g., NMDA/GABA_A modulation), may affect sleep, mood, or cognition—use caution in patients with unstable psychiatric illness.
 - Monitor in cardiovascular/metabolic risk patients: Both hormones can affect lipid profiles and insulin sensitivity.
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Adverse Reactions:

- Enclomiphene: Hot flashes, headache, visual disturbances, mood swings; risk of VTE
 - Pregnenolone: Insomnia, agitation/activation, dizziness, acne or oily skin, GI upset
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Interactions:

- May interact with exogenous hormone therapy (additive effects).
 - Potential interaction with other estrogenic or anti-estrogenic drugs; caution with hepatically metabolized drugs (CYP involvement).
 - Theoretical additive hormonal effects; monitor carefully when used with TRT, aromatase inhibitors, or fertility drugs.
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Use in Specific Populations:

- Pregnancy/Lactation: Contraindicated.
 - Men: Investigational use for secondary hypogonadism and fertility preservation.
 - Older adults: Sometimes compounded for “anti-aging,”; use caution with CV/metabolic risks.
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Storage:

- Store in original container at room temperature (up to 30°C or 86°F)
 - Store in a cool dry place away from heat, sunlight, and moisture
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Monitoring Parameters:

- Hormonal labs: Testosterone (total & free), estradiol, LH, FSH, SHBG.
 - Pregnenolone supplementation: Consider periodic steroid panel if high doses or long-term use.
 - Metabolic safety: Lipid panel, fasting glucose, BP.
 - Safety monitoring: Watch for visual disturbances or thromboembolic symptoms.
 - Clinical outcomes: Libido, energy, mood, fertility parameters (sperm count, motility).
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Citations:

1. Lin YC, Cheung G, Porter E, Papadopoulos V. The neurosteroid pregnenolone is synthesized by a mitochondrial P450 enzyme other than CYP11A1 in human glial cells. *J Biol Chem.* 2022;298(7):102110. doi:10.1016/j.jbc.2022.102110
 2. Wexler TL. Enclomiphene Citrate Improves Hormone Levels While Preserving Sperm Production in Men With Secondary Hypogonadism. *Fertil Steril.* 2014;102(3):720-727. Updated May 11, 2016. Accessed August 20, 2025.
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