

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Testosterone/Estradiol

Form: Topical Cream

Drug Class:

- Testosterone: Androgen; Anabolic Steroid
 - Estradiol (E2): Estrogen; agonist at estrogen receptors
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Mechanism of Action^{1,2,:}

When compounded together, Testosterone/Estradiol can create a synergistic network that optimizes cellular signaling across multiple systems, supporting comprehensive hormonal health and overall wellbeing. It is intended to:

- Activate androgen receptors to improve libido, energy, mood, muscle protein synthesis, and bone remodeling.
 - Restore hormonal balance by replacing declining sex steroids to improve vasomotor symptoms, sexual function, and quality of life.
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Indications Commonly Prescribed For:

- Primary and secondary hypogonadism in adult males
 - Delayed puberty in adolescent males (under specialist supervision)
 - Hormone therapy in transgender men
 - Estrogen-androgen balance correction in cases of estrogen dominance
 - Hypoactive sexual desire disorder in postmenopausal women
 - Androgen insufficiency symptoms
 - Menopausal hormone therapy (MHT)
 - Bone and metabolic health
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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 components.
 - Thromboembolic disorders or recent events (e.g., DVT, PE, stroke, MI).
 - Men with carcinoma of the breast, known or suspected prostate cancer.
 - Severe untreated obstructive sleep apnea, uncontrolled heart failure, significant polycythemia.
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Cautions: Let your Healthcare provider know if you experience any adverse side effects.

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How to Use: This compounded preparation is in the form of a topical cream. The cream is a special container that will administer 0.25ml dose. Clean desired area prior to use. To administer remove the protective covering on the top of the dispenser. Turn the dosing knob in the direction marked for the number of prescribed clicks. Confirm the cream has exited the holes at the top of the dispenser. Apply the cream by rubbing the dispenser (where cream exited the holes) onto the desired area. Continue to rub the area until the cream is evenly dispersed over the desired area. Replace the protective cover with a light push and store the device until next dose. If you miss a dose apply as soon as you remember, but not at the time for the next dose. The desired results may take up to several weeks.

Warnings and Precaution:

- Cardiovascular Risks: Potential increased risk of heart attack and stroke; monitor patients.
 - Use cautiously/avoid in patients with hormone-sensitive malignancies.
 - Hepatic Effects: Monitor liver function periodically.
 - Androgenic adverse effects in women (acne, hirsutism, alopecia, voice deepening).
 - Venous thromboembolism (VTE) and cardiovascular risks are higher with oral administration due to first-pass hepatic effects; lower with transdermal routes.
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Adverse Reactions:

Common:

- Skin irritation
- Acne
- Mood swings

Serious, But Rare:

- Cardiovascular events
 - Liver toxicity
 - Gynecomastia
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Interactions:

- Anticoagulants: Testosterone may enhance the effects of oral anticoagulants.
 - CYP3A4 modulators: May alter testosterone metabolism.
 - Insulin: Testosterone may decrease blood glucose levels; watch glycemic control.
 - Estradiol can induce hepatic protein synthesis and impact drugs metabolized by liver enzymes.
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Use in Specific Populations:

- Geriatric: May increase the risk of prostate enlargement and cardiovascular events.
 - Pregnant/Breastfeeding: Contraindicated
 - Liver or renal impairment: Use caution and monitor labs more frequently.
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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:

- Hormone panels
 - Prostate-specific antigen (PSA) levels and digital rectal exams for prostate monitoring
 - Routine labs: Lipid profile, liver function, and blood pressure
 - Hematocrit and hemoglobin levels to detect polycythemia
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Citations:

1. Tyagi V, Scordo M, Yoon RS, Liporace FA, Greene LW. Revisiting the role of testosterone: Are we missing something? *Rev Urol.* 2017;19(1):16-24. doi: 10.3909/riu0716. PMID: 28522926; PMCID: PMC5434832.
2. Kovács T, Szabó-Meleg E, Ábrahám IM. Estradiol-Induced Epigenetically Mediated Mechanisms and Regulation of Gene Expression. *International Journal of Molecular Sciences.* 2020; 21(9):3177. <https://doi.org/10.3390/ijms21093177>