

PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Testosterone

Form: Topical Cream

Drug Class: Androgen; Anabolic Steroid

Mechanism of Action^{1,2}:

Compounded testosterone is a bioidentical androgen intended to mimic your body's natural testosterone by binding to androgen receptors in various tissues, such as the muscles, bones, and reproductive tissues. Once bound, the receptor-hormone complex may attach to DNA and regulate gene expression, triggering the production of proteins that promotes the development and maintenance of male secondary sexual characteristics, anabolic activity, and overall hormonal balance.

Indications Commonly Prescribed For:

- Primary and secondary hypogonadism in adult males.
 - Delayed puberty in adolescent males (under specialist supervision).
 - Hormone therapy in transgender men.
 - Hypoactive sexual desire disorder in postmenopausal women.
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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 testosterone.
 - Men with carcinoma of the breast, known or suspected prostate cancer.
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Cautions: Let your Healthcare provider know if you experience any adverse side effects.

Warnings and Precautions:

- **Cardiovascular Risks:** Potential increased risk of heart attack and stroke; monitor patients with cardiovascular disease.
 - **Prostate Monitoring:** Regular screening for prostate abnormalities is recommended.
 - **Hepatic Effects:** Monitor liver function periodically.
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Adverse Reactions: If you experience any side effects or adverse reactions, including those not listed, please contact your healthcare provider. Seek emergency care if symptoms are severe.

Common:

- Skin irritation
- Acne
- Mood swings
- Increased red blood cell count

Serious, But Rare:

- Cardiovascular events
 - Liver toxicity
 - Prostate abnormalities
 - Gynecomastia
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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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Interactions:

- Anticoagulants: Testosterone may enhance the effects of oral anticoagulants.
 - Corticosteroids: Concurrent use may increase fluid retention.
 - Insulin: Testosterone may decrease blood glucose levels, necessitating adjustment of insulin dosage.
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Use in Specific Populations:

- Pediatric: Safety and efficacy have not been established; use with caution.
 - Geriatric: May increase the risk of prostate enlargement and cardiovascular events.
 - Females: Use in women should be approached with caution due to potential virilizing effects.
 - Pregnant/Breastfeeding: Contraindicated
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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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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

Monitoring Parameters:

- Serum testosterone levels to ensure therapeutic range.
 - Prostate-specific antigen (PSA) levels and digital rectal exams for prostate monitoring.
 - Liver function tests.
 - Hematocrit and hemoglobin levels to detect polycythemia.
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Citations:

1. Nassar GN, Leslie SW. Physiology, Testosterone. [Updated 2022 Jan 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK526128/> 2.
 2. 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.
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