PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Progesterone/DHEA/Testosterone/Estradiol/Estriol
Form: Topical Cream

Drug Class:

- Progesterone: Progestin (Natural Steroid Hormone)
- DHEA: Endogenous androgen/estrogen precursor
- Testosterone**:** Androgen; Anabolic Steroid
- Estradiol (E2): Estrogen; agonist at estrogen receptors
- Estriol (E3): Estrogen; agonist at estrogen receptors

Mechanism of Action[1,2,3,4,5]**:**

When compounded together, Progesterone/DHEA/Testosterone/Estradiol/Estriol 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.
- Serve as upstream hormone precursor that tissues convert into androgens and estrogens, supporting sexual function, bone integrity, and wellbeing.

Indications Commonly Prescribed For:

- Primary and secondary hypogonadism in adult males
- 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

Before Use: Let your healthcare provider know if you have any medication allergies before you take this compounded preparation. Let your healthcare 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).
- Undiagnosed abnormal genital bleeding or endometrial hyperplasia.
- Men with carcinoma of the breast, known or suspected prostate cancer.
- Severe untreated obstructive sleep apnea, uncontrolled heart failure, significant polycythemia.

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. Place the jar on a flat surface. Using clean, dry hands, gently press down on the top of the pump. This will dispense a measured amount of cream through the center opening. Confirm the cream has exited the holes at the top of the dispenser. Apply the cream onto the desired area. Continue to rub the area until the cream is evenly dispersed over the desired area. Replace the protective cover 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).
- Lipid effects: DHEA may lower HDL cholesterol; assess in cardiovascular risk patients.
- Venous thromboembolism (VTE) and cardiovascular risks are higher with oral administration due to first-pass hepatic effects; lower with transdermal routes.

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
- Breast tenderness
- Bloating, nausea
- Headache
- Fluid retention
- Irregular bleeding

Serious, But Rare:

- Cardiovascular events
- Liver toxicity
- Thromboembolism
- Gynecomastia
- Breast/endometrial cancer risk
- Gallbladder disease
- Endometrial hyperplasia

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 induces hepatic protein synthesis and may impact drugs metabolized by liver enzymes.
- Potential interaction with thyroid hormones (may affect binding globulins)

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.
- Postmenopausal women: Commonly used for vaginal symptoms with fewer systemic 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.

Monitoring Parameters:

- Hormone and thyroid 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

Citations:

1. Cable JK, Grider MH. Physiology, Progesterone. [Updated 2022 May 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK558960/
2. Sigel A, Michalkova D, Capdevila A. Pharmacological activities of dehydroepiandrosterone: a review. Clin Endocrinol (Oxf). 2019;90(4):633s–642. doi:10.1530/EC-19-0155
3. 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.
4. 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
5. Clark JH, Markaverich BM. The agonistic and antagonistic actions of estriol. J Steroid Biochem. 1984;20(5):1005-1013. doi:10.1016/0022-4731(84)90011-6.