PRESCRIPTION MONOGRAPH

Compounded Active Ingredients: Progesterone/DHEA
Form: Oral Capsule

Drug Class:

- Progestogens (Natural Steroid Hormone)
- DHEA
    - Endogenous steroid hormone precursor
    - Prohormone converted into estrogens and androgens

Mechanism of Action[1,2,3]: Adding DHEA to standard progesterone regimens has been shown to potentially further raise testosterone/estradiol and modify neurosteroids (e.g., allopregnanolone) vs HRT alone.

- DHEA is intended to:
    - Convert into androstenedione, testosterone, and estrogen.
    - Enhance libido, energy, and immune function.
    - Reduce age-associated decline linked to fatigue and cognitive issues.
- Progesterone is intended to:
    - Bind to progesterone receptors in target tissues, inducing secretory changes in the endometrium, promoting mammary gland development, relaxing uterine smooth muscle, and maintaining pregnancy.
    - Exhibit antigonadotrophic effects by suppressing pituitary gonadotropin secretion, thereby inhibiting follicular maturation and ovulation.

Indications Commonly Prescribed for:

- Genitourinary syndrome of menopause (GSM)/dyspareunia
- Menopausal symptom management
- Luteal support in FET cycles
- Complement systemic HRT (DHEA)

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 progesterone or DHEA.
- Undiagnosed abnormal genital bleeding.
- History of breast cancer or other hormone-sensitive malignancies.
- Active or history of thromboembolic disorders (e.g., deep vein thrombosis, pulmonary embolism).
- Liver dysfunction or disease.
- Known or suspected pregnancy (when used for non-pregnancy-related indications).

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 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.

Warnings and Precautions:

- Cardiovascular Disorders: Progesterone therapy should not be used for the prevention of cardiovascular disease or dementia.
- Hormone-sensitive conditions: Use cautiously or avoid in patients with breast, uterine, ovarian, or prostate cancer – DHEA may stimulate hormone-dependent tumors.
- Probable Dementia: Elevated risk in postmenopausal women aged 65 and older receiving combined therapy.
- Mood Disorders: Use with caution in patients with a history of depression; monitor for exacerbation of symptoms.
- Fluid Retention: Exercise caution in patients with conditions that may be exacerbated by fluid retention, such as epilepsy, migraine, asthma, cardiac or renal dysfunction.
- Lipid effects: DHEA may lower HDL cholesterol; assess in cardiovascular risk patients.
- Sedation/dizziness: Take at bedtime; caution driving/operating machinery.

Adverse Reactions:

- Progesterone:
  - Headache, Drowsiness, Dizziness
  - Breast tenderness
  - Bloating, Fluid retention
  - Mood swings
- DHEA
  - Acne, oily skin, hair changes
  - Irritability
  - HDL reduction
  - Hirsutism

Interactions:

- DHEA may affect CYP3A4 metabolism, increasing levels of numerous drugs (e.g., corticosteroids, statins, immunosuppressants).
- Herbal Products (e.g., St. John's Wort): May reduce progesterone effectiveness by inducing hepatic enzymes.
- Monitor closely when co-administered with topical or systemic estrogens/testosterone due to additive effects.

Use in Specific Populations:

- Pregnancy: Use only if clearly needed and prescribed by a healthcare provider.
- Lactation: Progesterone is excreted in breast milk; caution is advised.
- Pediatrics: Safety and efficacy have not been established in pediatric patients.
- Geriatrics: Use with caution; increased sensitivity in some older individuals cannot be ruled out.
- Adrenal insufficiency: Oral DHEA is sometimes used to restore physiologic levels.
- Hepatic impairment: Both labels note limited PK data; metabolized hepatically—use caution.

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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:

- Regular physical examinations, including breast and pelvic exams.
- Monitoring for signs of thromboembolic disorders.
- Assessment of mood changes or depressive symptoms.
- Periodic liver function tests in long-term use.
- Periodic assessment of hormone-sensitive organ status (e.g., breast, prostate).
- Evaluate lipid profile, liver function, hematocrit, and monitor for mood or skin change.

Citations:

1. Sigel A, Michalkova D, Capdevila A. Pharmacological activities of dehydroepiandrosterone: a review. Clin Endocrinol (Oxf). 2019;90(4):633–642. doi:10.1530/EC-19-0155
2. 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/
3. Pluchino N, Ninni F, Stomati M, et al. One-year therapy with 10 mg/day DHEA alone or in combination with HRT in postmenopausal women: Effects on hormonal milieu. *Maturitas*. 2008;59(3):293–303. doi:10.1016/j.maturitas.2008.02.004