

Brand Name: PROSTO-300 SR

Composition: natural micronized progesterone sustained release tablet 300mg

Dosage Form: TABLET

Category: Hormonal Therapy / Progestin

Packaging Type: ALU-ALU

Packaging: 10 x 1 x 10

Brief Product Introduction:

PROSTO-300 SR is a sustained-release progesterone tablet manufactured by **AstraEureka Pharmaceutical**, formulated with 300 mg of natural micronized progesterone. It is used in hormone replacement therapy (HRT), management of menstrual disorders, and support of early pregnancy in assisted reproductive technology (ART) cycles. The sustained-release formulation ensures a prolonged therapeutic effect and consistent hormone levels.

Composition:

Each film coated sustained release tablet contains:

Progesterone IP (Natural Micronized).....300 mg
Excipients.....q.s.

Key Ingredients:

- **Natural Micronized Progesterone (300 mg):** Bioidentical to endogenous human progesterone, allowing efficient hormonal support with improved absorption.
- **Pharmaceutical Excipients (q.s.):** Ensure controlled release and tablet integrity.

Key Benefits:

1. Supports luteal phase and early pregnancy in fertility treatments
2. Manages menstrual irregularities and amenorrhea
3. Essential in hormone replacement therapy during menopause
4. Reduces risk of endometrial hyperplasia during estrogen therapy
5. Mimics natural progesterone, leading to better tolerance

Indications:

1. Luteal phase support in IVF and ART procedures
2. Secondary amenorrhea
3. Hormone replacement therapy in postmenopausal women (in combination with estrogen)

4. Menstrual irregularities due to progesterone deficiency
5. Prevention of endometrial hyperplasia during estrogen therapy

Directions for Use:

- To be taken orally with or without food
- Swallow whole with water; do not crush or chew
- Follow the prescribed dosage and schedule by the physician
- Preferably taken at the same time daily

Dosage and Administration:

- **General Dose:** One tablet (300 mg) once daily or as directed by the physician
- **Luteal Phase Support / ART:** Dose and duration may vary based on hormonal monitoring
- **Amenorrhea / HRT:** Often cyclic administration (10–14 days per month) alongside estrogen
- Dose adjustment may be required based on clinical condition and patient response

Mechanism of Action:

- Progesterone is a steroid hormone essential for the regulation of ovulation and menstruation.
- In pregnancy, it prepares the endometrium for implantation and supports early gestation.
- PROSTO-300 SR, containing **natural micronized progesterone**, binds to progesterone receptors in target tissues, including the uterus, breast, and brain.
- It transforms the proliferative endometrium into a secretory one, supports embryo implantation, and maintains pregnancy.
- The sustained-release formulation ensures a prolonged plasma level, simulating the natural cyclic pattern.

Contraindications:

1. Known hypersensitivity to progesterone or excipients
2. Liver dysfunction or disease
3. Undiagnosed vaginal bleeding
4. History of breast or genital cancer
5. Active or history of thromboembolic disorders
6. Missed abortion

Side Effects:

- Drowsiness, dizziness
- Bloating, abdominal cramps
- Breast tenderness
- Mood swings, headache
- Nausea
- Weight changes
- Rarely, allergic reactions or thrombotic events

Safety Information:

1. Use only under medical supervision
2. Regular monitoring recommended during long-term use
3. Not to be used as emergency contraception
4. Caution in patients with a history of depression
5. Avoid alcohol or sedatives that can increase drowsiness
6. Inform the physician if pregnant or breastfeeding

Important Notice:

- PROSTO-300 SR is a prescription medication.
- It should be used strictly as advised by a healthcare professional.
- Not suitable for self-medication or emergency contraception.
- Regular follow-up and hormonal assessment are essential for safety and efficacy.

Storage Condition:

- Store in a cool, dry place below 25°C
- Protect from light and moisture
- Keep out of reach of children
- Do not use expired tablets

Packing Information:

- **Packaging Type:** ALU-ALU
- **Pack Size:** 10 x 1 x 10 tablets mono with outer box