

Smilepill Ultra Tablet

Ethinyl Estradiol (0.03 mg) + Drospirenone (3 mg) Tablet

Description:

Ethinyl Estradiol (0.03 mg) + Drospirenone (3 mg) tablet is a combination oral contraceptive containing Ethinyl Estradiol, a synthetic estrogen, and Drospirenone, a synthetic progestin with anti-androgenic properties.

Composition:

- **Ethinyl Estradiol: 0.03 mg**
 - **Drospirenone: 3 mg**
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Indications:

- 1. Contraception:**
 - **For the prevention of pregnancy in women who prefer an oral contraceptive.**
- 2. Management of Acne:**
 - **For the treatment of moderate acne, especially in women with androgen excess (e.g., elevated testosterone levels).**
- 3. Management of Polycystic Ovary Syndrome (PCOS):**
 - **For the regulation of menstrual cycles and treatment of symptoms such as irregular periods, hirsutism, and acne associated with PCOS.**
- 4. Premenstrual Dysphoric Disorder (PMDD):**
 - **For the treatment of PMDD, a severe form of premenstrual**

syndrome (PMS) characterized by extreme mood changes, irritability, and depression.

5. Management of Fluid Retention:

- **Due to Drospirenone's mild diuretic effect, it may help reduce fluid retention and associated bloating.**
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Dosage and Administration:

- **Adults:**
 - **Take 1 tablet daily at the same time every day, preferably with food, for 21 consecutive days, followed by a 7-day break (during which withdrawal bleeding typically occurs). After the break, begin a new pack of tablets.**
 - **Starting the Tablet:**
 - **If starting on day 1 of the menstrual cycle: Start taking 1 tablet daily from day 1 of the menstrual cycle.**
 - **If starting after a break (e.g., post-birth control pill): Follow your healthcare provider's instructions for transitioning.**
 - **Missed Dose:**
 - **If you miss a dose, take it as soon as you remember unless it is already time for the next dose. If you miss two or more doses, consult your healthcare provider for instructions. If you miss several days, you may need to use additional contraception.**
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Side Effects:

- **Common:**
 - Nausea, vomiting, headache, breast tenderness, weight changes, mood swings, and irregular spotting or breakthrough bleeding during the first few months of use.
 - Acne or changes in skin complexion (initially).
 - Decreased libido or changes in sexual drive.
 - Fluid retention or bloating.
- **Serious but Rare:**
 - Venous thromboembolism (blood clots), especially in smokers, overweight women, or women over 35 years old.
 - Heart attack or stroke due to increased risk of thromboembolic events.
 - Liver problems: Symptoms like jaundice, dark urine, or persistent abdominal pain.
 - Severe allergic reactions: Rash, swelling, or difficulty breathing.

Precautions:

1. **Thromboembolic Disorders:**
 - Use with caution in women with a history of blood clots, stroke, heart disease, or other risk factors for thromboembolic events (e.g., smoking, obesity, over 35 years old).
2. **Liver Disease:**
 - Use with caution in women with liver disease. Regular monitoring of liver function may be necessary.
3. **Pregnancy and Breastfeeding:**
 - **Pregnancy:** This medication is contraindicated during pregnancy and should not be used if pregnancy is suspected or confirmed.
 - **Breastfeeding:** Drospirenone and Ethinyl Estradiol can pass into breast milk, so caution is advised.

Consult a healthcare provider before using this medication during breastfeeding.

4. Smoking:

- Smoking increases the risk of serious cardiovascular events (such as blood clots, stroke, and heart attack) while using combined oral contraceptives, especially in women over 35 years old.

5. Other Conditions:

- Caution is advised if you have a history of depression, hypertension, diabetes, migraine, or gallbladder disease, as hormonal contraceptives may exacerbate these conditions.

Storage:

- Store at room temperature (15-30°C), away from light, heat, and moisture.
- Keep the tablets in their original packaging to protect from moisture.
- Keep out of the reach of children.

Note:

This medication must be taken as prescribed and at the same time every day for optimal effectiveness. If you experience any adverse effects or unusual symptoms, contact your healthcare provider immediately.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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