

Pristil

Ulipristal Acetate 5 mg

Presentation

Pristil : Each tablet contains 5 mg Ulipristal Acetate.

Description

Pristil tablet contains Ulipristal Acetate, which is an orally-active synthetic selective progesterone receptor modulator characterized by a tissue-specific partial progesterone antagonist effect. When administered in recommended dose this medicine acts by modifying the activity of progesterone, a naturally occurring hormone in the body. It is used either before an operation of fibroids or for long term treatment of fibroids to reduce their size, to stop or reduce bleeding and to increase the red blood cell count. Ulipristal Acetate is rapidly absorbed from GIT after oral administration. Ulipristal Acetate is metabolized and conjugated in the liver.

Indications and Uses

1. Preoperative treatment of moderate to severe symptoms of uterine fibroids (commonly known as myomas) in adult women of reproductive age
2. Intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

Dosage and Administration

The treatment consists of one tablet of 5 mg to be taken orally once daily for treatment courses of up to 3 months each. Tablets may be taken with or without food.

Treatments should only be initiated when menstruation has occurred:

- The first treatment course should start during the first week of menstruation.
- Re-treatment courses should start at the earliest during the first week of the second menstruation following the previous treatment course completion.

Menstrual cycle starts within 4 weeks after stopping intake of Ulipristal Acetate. Repeated intermittent treatment has been studied up to 4 intermittent courses.

If a dose is missed Ulipristal Acetate should be taken as soon as possible. If the dose was missed by more than 12 hours, the missed dose must be skipped and simply resume the usual dosing schedule.

Side Effects:

Reduction or absence of menstrual bleeding (amenorrhea), endometrial thickening, headache, vertigo, stomach ache, nausea, acne, muscle and bone pain, ovarian cyst, breast tenderness/pain, pelvic pain, hot flushes, tiredness, weight increase, dry mouth, constipation, uterine bleeding may occur.

Precautions

1. Concomitant use of progestin-only pills, a progestogen-releasing intrauterine device or combined oral contraceptive pills is not recommended.
2. Severe asthma, liver or kidney disease.
3. Concomitant use of Ulipristal Acetate and potent CYP3A4 inducers (e.g. rifampicin, rifabutin, carbamazepine, phenytoin, Phenobarbital etc.) is not recommended.

Pregnancy and Lactation

Pregnancy: Ulipristal Acetate is contraindicated during pregnancy. There are no or limited amount of data from the use of Ulipristal Acetate in pregnant women.

Lactation: Ulipristal Acetate is excreted in human milk. Ulipristal Acetate is contraindicated during breast-feeding

Ulipristal Acetate should not be taken by children under 18 years of age.

Contraindications

Undiagnosed vaginal bleeding, not caused by uterine fibroids

Known or suspected pregnancy

Breastfeeding

Cancer of the uterus, cervix, ovary or breast.

Known sensitivity to Ulipristal Acetate or to any of the excipients

Drug Interactions

Potential for other medicinal products to affect Ulipristal Acetate: Hormonal contraceptives (medicinal products containing progestogen), CYP3A4 inhibitors (ketoconazole, erythromycin etc.), CYP3A4 inducers (rifampicin, carbamazepine, phenobarbital, phenytoin etc.), Proton Pump Inhibitor, P-gp substrates (dabigatran etexilate, digoxin, fexofenadine).

Overdose

Experience with Ulipristal Acetate overdose is limited. Daily doses of 50 mg for 10 consecutive days were administered to a limited number of subjects, and no severe or serious adverse reactions were reported.

Storage

Store at or below 30°C in a cool dry, place

Keep away from light and out of the reach of children

Commercial Pack

Pristil : Each blister contains 10 tablets. Each carton contains 2 blisters of 20 tablets.



Manufactured by

Incepta Pharmaceuticals Ltd

Savar, Dhaka, Bangladesh

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