

Uliroid

Ulipristal Acetate INN
5 mg Tablet



Composition

Uliroid 5 mg tablet: Each tablet contains Ulipristal Acetate INN 5 mg.

Pharmacology

Uliroid (Ulipristal Acetate) is an orally-active synthetic Selective Progesterone Receptor Modulator (SPRM) characterized by a progesterone antagonist effect. Ulipristal Acetate exerts a direct effect on the endometrium. When administered daily during a menstrual cycle, most women will complete their first menstruation but will not menstruate again until the treatment is stopped. Menstrual cycle generally resume within 4 weeks. Ulipristal Acetate reduces the fibroid size through inhibition of cell proliferation and induction of apoptosis.

Indication

Uliroid (Ulipristal Acetate) is indicated for pre-operative & intermittent treatment of moderate to severe symptoms of uterine fibroids.

Dosage and administration

Treatment with **Uliroid** should be started during the first week of menstruation. One tablet should be taken once daily for up to three months. This 3 months treatment course can be repeated 3 times. Retreatment should be started within 1st week of 2nd menstrual cycle after previous course. If a patient missed a dose, the patient should take **Uliroid** as soon as possible. If the dose was missed by more than 12 hours, the patient should not take the missed dose and simply resume the usual dosing schedule.

Warnings and precautions

Ulipristal Acetate should only be prescribed after careful diagnosis.

Contraception: Concomitant use of progesterone-only pills, progesterone-releasing intrauterine device or combined oral contraceptive pills is not recommended, a non hormonal contraceptive method is recommended during treatment.

Endometrial changes: Changes in the histology of the endometrium may be observed in patients treated with Ulipristal Acetate. These changes are reversible after treatment cessation and should not be mistaken for endometrial hyperplasia.

Bleeding pattern: Ulipristal Acetate usually leads to a significant reduction in menstrual blood loss or amenorrhea within the first 10 days of treatment. If an altered persistent or unexpected bleeding pattern occurs, such as inter-menstrual bleeding, investigation of the endometrium including endometrial biopsy should be performed in order to exclude other underlying conditions.

Asthma patients: Use in women with severe asthma insufficiently controlled by oral Glucocorticoids is not recommended.

Contraindications

Ulipristal Acetate is contraindicated in the following cases-

- Hypersensitivity to Ulipristal Acetate
- Women with abnormal vaginal bleeding of unknown cause
- Women with uterine, cervical, ovarian or breast cancer
- Pregnancy
- Breastfeeding

Side-effects

The majority of the adverse reactions are mild to moderate & do not lead to discontinuation of the drug & usually resolves spontaneously. Among them the most common side-effects are- headache, vertigo, abdominal pain, excessive sweating, hot flashes, acne, muscle or bone pain, breast tenderness, excessive bleeding from the uterus, fatigue, ovarian cyst etc.

Drug interaction

Ulipristal Acetate interacts with the following drugs- Erythromycin, Rifampicin, Rifabutin, Verapamil, Ketoconazole, Ritonavir, Nefazodone, Itraconazole, Telithromycin, Clarithromycin, Carbamazepine, Oxcarbazepine, Phenytoin, Fosphenytoin, Phenobarbital and Primidone.

Pregnancy and lactation

Ulipristal Acetate is contraindicated during pregnancy.

Ulipristal Acetate is excreted in human milk. The effect on newborn/infants has not been studied. Thus, Ulipristal Acetate is contraindicated during breastfeeding.

Pediatric use

There is no relevant use of Ulipristal Acetate in the pediatric population.

Renal impairment

No dose adjustment is recommended in patients with mild or moderate renal impairment. In the absence of specific studies, Ulipristal Acetate is not recommended in patients with severe renal impairment unless the patient is closely monitored.

Hepatic impairment

No dose adjustment is recommended for patients with mild hepatic impairment. In the absence of specific studies, Ulipristal Acetate is not recommended in patients with moderate or severe hepatic impairment unless the patient is closely monitored.

Overdose

Experience with Ulipristal Acetate overdose is limited. Single doses up to 200 mg and 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 25°C. Protect from moisture and light.

Packaging

Each box contains 2x10's tablets in blister strip.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh