

Fibropress®

Ulipristal Acetate

Tablet

Description

Ulipristal Acetate, is a selective progesterone receptor modulator. In some women, progesterone may promote the growth of fibroids, which may cause symptoms such as heavy uterine bleeding, anemia and abdominal pain. When progesterone activity is blocked, fibroid cells stop dividing and eventually die, which reduces the size of the fibroids and reduces the symptoms caused by them.

Indications

Ulipristal Acetate is indicated for pre-operative and 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.

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.

The treating physician should explain to the patient the requirement for treatment free intervals.

Repeated intermittent treatment has been studied up to 4 intermittent courses.

Side Effects

Headache, Vertigo, Abdominal pain, Nausea,

Acne, Musculoskeletal pain, Hot flush, Pelvic pain, Breast tenderness/pain, Fatigue, Ovarian cyst.

Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- Pregnancy and breastfeeding.
- Genital bleeding of unknown aetiology or for reasons other than uterine fibroids.
- Uterine, cervical, ovarian or breast cancer.

Drug Interactions

The following medicines may interact with Ulipristal Acetate:

Erythromycin propionate, ketoconazole, ritonavir, nefazodone, rifampicin, carbamazepine, phenytoin, esomeprazole, digoxin, dabigatran etexilate, verapamil, itraconazole, telithromycin, clarithromycin, fexofenadine, rifabutin, oxcarbazepine, fosphenytoin, phenobarbital, primidone, efavirenz, nevirapine

The following types of medicine may interact with Ulipristal Acetate:

cytochrome P450 enzyme inhibitors, cytochrome P450 enzyme inducers, hormonal contraceptives, proton pump inhibitors, glycoprotein substrates, progestogens, medicines that affect gastric pH.

Use in Special Population

Pregnancy and Lactation

Contraindicated in Pregnant and Lactating mother.

Paediatric Use

Not use in patients below age 18 years.

Missed Dose

If a patient misses a dose, the patient should take Ulipristal Acetate 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.

Overdose

No severe or serious adverse reactions were reported during overdose of Ulipristal Acetate.

Pharmaceutical Precautions

Keep in a cool & dry place. Protect from light. Keep out of the reach of children.

Commercial Pack

Fibropress® Tablet: Box containing 10 tablets in 1X10's blister strips. Each tablet contains Ulipristal acetate INN 5 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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