Utal™

Ulipristal Acetate INN 5 mg

Composition
Each tablet contains Ulipristal Acetate INN 5 mg.

Pharmacology
The active substance in **Utal**™, ulipristal acetate, is a selective progesterone receptor modulator. It acts by blocking the receptor of a hormone in the body called progesterone, which is involved in controlling the growth of the lining of the womb. In some women, progesterone may promote the growth of fibroids, which may cause symptoms such as heavy uterine bleeding, anaemia 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.

Indication
Utal™ is used before surgery to treat moderate to severe symptoms of uterine fibroids, which are noncancerous (benign) tumors of the womb (uterus). **Utal**™ is used in adult women who have not yet reached menopause.

Dosage & Administration
Utal™ is taken by mouth and the recommended dose is one tablet a day for up to three months. The three month treatment can be repeated but only once. Treatment should always be started during the first week of the menstrual cycle (period bleeding).

Contraindication
- 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.

Use in pregnancy & Lactation
Pregnancy Category **X**. Ulipristal acetate is contraindicated during pregnancy. Ulipristal acetate is excreted in human milk and is not recommended.

Side effects
- Endometrial thickening
- Hot flush
- Headache
- Uterine haemorrhage

Precautions
Ulipristal acetate should only be prescribed after careful diagnosis. Pregnancy should be precluded prior to
treatment.
- Contraception
- Renal impairment
- Hepatic impairment
- Asthma patients
- Endometrial changes

Patients should be informed that treatment with ulipristal acetate usually leads to a significant reduction in menstrual blood loss or amenorrhea within the first 10 days of treatment. If the excessive bleeding persist, patients should notify their physician. Menstrual periods will generally return within 4 weeks after the end of the treatment course

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
Keep protected from light & moisture, store below 25° C. Keep out of reach of children.

How Supplied
Each box contains 20 tablets in alu-PVDC blister pack.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
BANGLADESH