



#### COMPOSITION

**Orili™ 200 Tablet:** Each film coated tablet contains Elagolix 200 mg as Elagolix Sodium INN.

#### PHARMACOLOGY

Elagolix is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of Elagolix results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of the ovarian sex hormones, estradiol and progesterone.

#### INDICATION

**Orili™ 200** is indicated for the management of moderate to severe pain associated with endometriosis.

#### DOSAGE & ADMINISTRATION

Pregnancy should be excluded before starting treatment with elagolix and start elagolix within 7 days from the onset of menses. Initial treatment with elagolix 200 mg twice daily up to 6 months (with coexisting dyspareunia). Treatment with elagolix 200 mg should not exist more than 6 months as it may decrease bone mineral density (BMD). In case of moderate to severe hepatic impairment elagolix 200 mg is not recommended.

#### CONTRAINDICATION

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.
- Women who are suspected to be, or may become pregnant during the course of therapy
- Women with undiagnosed vaginal bleeding
- Women with known osteoporosis, due to the risk of further bone loss

#### WARNING & PRECAUTIONS

##### *Decrease in Bone Mineral Density:*

Elagolix causes a dose-dependent decrease in bone mineral density (BMD). BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment.

##### *Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy:*

Women who take elagolix may experience a reduction in the amount, intensity or duration of menstrual bleeding, which may reduce the ability to recognize the occurrence of a pregnancy in a timely manner. Perform pregnancy testing if pregnancy is suspected, and discontinue elagolix if pregnancy is confirmed. *Suicidal Ideation, Suicidal Behavior, and Exacerbation of Mood Disorders:*

Patients must seek medical attention for suicidal ideation, suicidal behavior, new onset or worsening depression, anxiety or other mood changes.

##### *Hepatic Transaminase Elevations:*

Dose-dependent elevations in serum alanine aminotransferase (ATL). Patients should be aware of the signs

and symptoms of liver injury.

##### *Reduced Efficacy with Estrogen-Containing Contraceptives:*

Based on the mechanism of action of elagolix, estrogen containing contraceptives are expected to reduce the efficacy of elagolix. The effect of progestin-only contraceptives on the efficacy of elagolix is unknown.

#### SIDE EFFECTS

The most common side effects of elagolix include: hot flashes or night sweats, headache, nausea, difficulty sleeping, absence of periods, anxiety, joint pain, depression and mood changes.

#### USE IN PREGNANCY AND LACTATION

##### *Use in pregnancy:*

Elagolix is contraindicated in women who are, suspect that they are, or may become pregnant during the course of therapy. Discontinue elagolix if pregnancy occurs during treatment.

##### *Use in lactation:*

Discontinue nursing or delay initiation of elagolix until the mother is no longer breastfeeding.

#### DRUG INTERACTIONS

May potentiate P-gp substrates (eg. Digoxin), CYP2C19 substrates (eg. Dose limit of Omeprazole is upto 40mg daily). May antagonize CYP3A substrates. Antagonizes oral Midazolam, Rosuvastatin; consider increasing their doses. May be antagonized by CYP3A inducers. Reduces efficacy with estrogen-containing contraceptives.

#### OVERDOSE

In case of overdose, patients should be monitored for any signs or symptoms of adverse reactions and initiate appropriate symptomatic treatment, as needed.

#### STORAGE CONDITION

Protect from moisture. Store below 30° C. Keep out of reach of children.

#### PACKAGING

**Orili™ 200 Tablet:** Each box contains 12 tablets in alu-alu blister strip.

Manufactured by



**SQUARE**

**PHARMACEUTICALS LTD.  
BANGLADESH**