



COMPOSITION

Orili™ 150 Tablet: Each film coated tablet contains Elagolix 150 mg as Elagolix Sodium INN.

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

DOSAGE & ADMINISTRATION

Route of Administration: Should be taken orally.

Pregnancy should be excluded before starting treatment with Elagolix and start Elagolix within 7 days from the onset of menses.

Initial treatment with Elagolix 150 mg once daily up to 24 months. But in case of moderate hepatic impairment up to 6 months.

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.

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.

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.

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 30⁰ C. Keep all medicines out of reach of children.

PACKAGING

Orili™ 150 Tablet: Each box contains 12 tablets in alu-alu blister pack.

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

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH