

Endolix™

Elagolix Sodium INN Film Coated Tablet

DESCRIPTION

Endolix™ is a preparation of Elagolix Sodium. It is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of Elagolix Sodium 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.

INDICATIONS

Management of moderate to severe pain associated with endometriosis.

DOSAGE AND ADMINISTRATION

- Normal liver function or mild hepatic impairment: 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months.
- Moderate hepatic impairment: 150 mg once daily for up to 6 months.

CONTRAINDICATIONS

- Pregnancy
- Known osteoporosis
- Severe hepatic impairment
- Strong organic anion transporting polypeptide (OATP) 1B1 inhibitors

SIDE EFFECTS

- Hot flushes and night sweats
- Headache
- Nausea
- Insomnia, anxiety, depression
- Amenorrhea
- Arthralgia

PRECAUTION AND WARNING

Dose and duration-dependent decreases in bone mineral density (BMD) that may not be completely reversible. Assess BMD in women with additional risk factors for bone loss. Elagolix Sodium may alter menstrual bleeding, which may reduce the ability to recognize pregnancy. Perform testing if pregnancy is suspected. Discontinue if pregnancy is confirmed.

DRUG INTERACTIONS

Elagolix Sodium is a weak to moderate inducer of cytochrome P450 (CYP) 3A. Co-administration with Elagolix Sodium may decrease plasma concentrations of drugs that are substrates of CYP3A. It is an inhibitor of efflux transporter P-glycoprotein (P-gp). Co-administration with Elagolix Sodium may increase plasma concentrations of drugs that are substrates of P-gp (e.g., digoxin).

USE IN PREGNANCY AND LACTATION

Contraindicated. There is no information on the presence of Elagolix Sodium or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. There are no adequate animal data on the excretion of Elagolix Sodium in milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Elagolix Sodium and any potential adverse effects on the breastfed child from Elagolix Sodium.

STORAGE

Store below 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Endolix™ 150 mg Tablet:

Each box contains 1 strip of 10 tablets. Each film coated tablet contains Elagolix Sodium INN equivalent to Elagolix 150 mg.

Endolix™ 200 mg Tablet:

Each box contains 1 strip of 10 tablets. Each film coated tablet contains Elagolix Sodium INN equivalent to Elagolix 200 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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