

R-Lix™

Relugolix INN Film Coated Tablet

DESCRIPTION

R-Lix™ is a preparation of Relugolix. Relugolix is a nonpeptide GnRH receptor antagonist that competitively binds to pituitary GnRH receptors, thereby, reducing the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and consequently testosterone.

INDICATIONS

For the treatment of adult patients with advanced prostate cancer.

DOSAGE AND ADMINISTRATION

A loading dose of 360 mg on the first day of treatment followed by 120 mg taken orally once daily, at approximately the same time each day. Can be taken with or without food. Instruct patients to swallow tablets whole and not to crush or chew tablets.

CONTRAINDICATIONS

None

SIDE EFFECTS

The most common side effects ($\geq 10\%$) and laboratory abnormalities ($\geq 15\%$) were: hot flush, glucose increased, triglycerides increased, musculoskeletal pain, hemoglobin decreased, alanine aminotransferase (ALT) increased, fatigue, aspartate aminotransferase (AST) increased, constipation, and diarrhea.

PRECAUTIONS AND WARNINGS

QT/QTc Interval Prolongation: Androgen deprivation therapy may prolong the QT interval.

Embryo-Fetal Toxicity: Relugolix can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception.

DRUG INTERACTIONS

- P-gp Inhibitors: Avoid co-administration. If unavoidable, take Relugolix first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions.
- Combined P-gp and Strong CYP3A Inducers: Avoid co-administration. If unavoidable, increase the Relugolix dose to 240 mg once daily.

USE IN PREGNANCY AND LACTATION

The safety and efficacy of Relugolix have not been established in females. The safety and efficacy of Relugolix at the recommended dose of 120 mg daily have not been established in females. There are no data on the presence of Relugolix in human milk, the effects on the breastfed child, or the effects on milk production. Relugolix and/or its metabolites were present in milk of lactating rats.

PHARMACEUTICAL PRECAUTION

Do not store above 25° C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

R-Lix™ Tablet: Box containing 3 blisters of 10 tablets each. Each film coated tablet contains Relugolix INN 120 mg.

SK+F

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
TONGI, GAZIPUR, BANGLADESH
TM TRADEMARK
PM09975 V01

