

# Reluciba™ 120

## Relugolix

### PRESENTATION

**Reluciba™ 120:** Each film coated tablet contains Relugolix INN 120 mg.

### DESCRIPTION

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

Relugolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

### DOSAGE & ADMINISTRATIONS

Recommended Dosage: 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.

Relugolix can be taken with or without food. Patients should be instructed to swallow tablets whole and not to crush or chew tablets.

### 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.

### CONTRAINDICATIONS

None.

### WARNINGS & PRECAUTIONS

**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.

### USE IN SPECIFIC POPULATION

#### *Pregnancy & Lactation*

The safety and efficacy of Relugolix at the recommended dose of 120 mg daily have not been established in females.

#### *Females and Males of Reproductive Potential*

Based on findings in animals and mechanism of action, Relugolix may impair fertility in males of reproductive potential.

#### *Pediatric Use*

The safety and efficacy of Relugolix in pediatric patients have not been established.

#### *Geriatric Use*

No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

### 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.

### STORAGE

Store below 30° C. Keep all medicine out of the reach of children.

### HOW SUPPLIED

**Reluciba™ 120:** Each box contains 30 tablets in blister pack.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH