

RELUVYX 120

Relugolix Tablets 120 mg

Presentation: Each film coated tablet contains:

Relugolix 120 mg
Excipients q.s.

Colour: Iron oxide red NF, Titanium dioxide USP

Pharmaceutical form: Film Coated Tablet

Indications: Relugolix Tablets 120 mg is indicated for the treatment of adult patients with advanced prostate cancer.

Dosage and administration: Treatment with Relugolix Tablets 120 mg should be initiated with a loading dose of 360 mg (three Tablets) on the first day, followed by a 120 mg (one tablet) dose taken once daily at Approximately the same time each day.

Method of administration: For oral administration only.

Contraindications: Hypersensitivity to the active substance or to any of the excipients used in formulation.

Warnings & precautions: Effect on QT/QTc interval prolongation Androgen deprivation therapy may prolong the QT interval. In patients with a history of or risk factors for QT prolongation and in patients Receiving concomitant medicinal products that might prolong the QT interval, physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating Relugolix Tablets 120 mg.

Drug interaction: P gp inhibitors: Co-administration of Relugolix Tablets 120 mg and oral P gp inhibitors should be avoided. Combined P gp and strong CYP3A inducers. Co-administration of Relugolix Tablets 120 mg with combined P gp and strong CYP3A inducers should be avoided.

Pregnancy & lactation:

Pregnancy: There is a limited amount of data from the use of relugolix in pregnant women. Studies in animals have shown that exposure to relugolix in early pregnancy may Increase the risk of early pregnancy loss.

Breastfeeding: No data are available regarding the presence of Relugolix or its metabolites in human milk or its effect on the breast-fed infant.

Symptoms and treatment of overdose: There is no known specific antidote for overdose with Relugolix Tablets 120 mg. In the event of an overdose, Relugolix Tablets 120 mg should be stopped, and general supportive measures should be undertaken until any clinical toxicity has diminished or resolved, taking into consideration the half- life of 61.5 hours.

Storage: Store below 30° C. Keep out of reach of children.

Pack size: 30 tablets are supplied in bottles.

Before prescribing, please consult full prescribing information available from Amneal Healthcare Pvt. Ltd. 9th Floor, 901 to 905, Iscon Elegance, S. G. Highway, Ahmedabad 380015, Gujarat, India

To be sold by retail on the prescription of an Oncologist only.