

Relugolix

Names

The generic drug name is relugolix (rel" ue goe' lix). The brand name is Orgovyx® is the brand name. There may be other be names for this medication.

Why Am I Taking Relugolix and How Do I Take This Medication?

This drug is used to treat advanced prostate cancer in adult men.

Relugolix is a tablet you take by mouth.

- It is usually taken once a day – try to take it around the same time each day.
- You can take it with or without food.
- Take it exactly as directed. Do not take more or less than your doctor prescribed.
- Swallow the tablets whole; **Do not split, chew, or crush them.**
- Missed dose: If you miss a dose by less than 12 hours, take the missed dose as soon as you remember. Then return to your regular schedule. If it has been more than 12 hours since you should have taken it, skip that dose and continue your regular scheduled dose the next day. Do not take a double dose to make up for a missed one.
- If you miss 7 days (or more) in a row, talk to your doctor before you start taking relugolix again; you may need to restart at a higher dose.
- Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom). Do not remove the desiccant (small packet included with medication to absorb moisture).

How Does it Work?

Relugolix is in a class of medications called gonadotropin-releasing hormone (GnRH) receptor antagonists. It decreases the amount of testosterone (male hormone) the body makes. Testosterone promotes the growth of some prostate cancers so decreasing testosterone may slow or stop the spread of the of the prostate cancer.

What Should I Tell My Doctor Before I Begin?

Tell your doctor if you:

- have had an allergic reaction to relugolix or if you have other allergies
- have or have ever had long QT syndrome (a rare heart problem causing irregular heartbeat, fainting, or sudden death); high or low blood levels of calcium, potassium, magnesium, or sodium; or heart failure

This drug may interact with other medications or cause harmful side effects. Tell your doctor and pharmacist about all prescription or over-the-counter medications, vitamins, or supplements that you are taking.

What Are Some Possible Side Effects?

- Hot flashes, flushing, and/or excessive sweating
- Changes in blood test results: Increased blood sugar, increased triglycerides, increased liver enzymes such as ALT and AST (measured on blood tests called liver function tests or LFTs), and decreased hemoglobin (the protein in red blood cells that carries oxygen to body's organs and tissues)
- Fatigue
- Muscle, back, joint, or bone pain
- Diarrhea, constipation
- Weight gain
- Problems falling or staying asleep, depression
- Loss of sexual ability and/or loss of interest in sex
- Gynecomastia (breast enlargement)
- Infertility, birth defects: May decrease fertility in men. Talk to your doctor about this risk

How Can I Manage These Side Effects?

- **Hot flashes/flushing:** Dress in layers, use a cool washcloth around your neck, or use a person-size fan (or a fan that sprays a light mist)
- **Fatigue:** Eat well and stay out of bed as much as possible during your treatment to stay strong. If you feel fatigued, take rest periods throughout the day, and try to limit your activities.
- **Muscle, joint, bone pain:** Talk to your doctor before taking any medication for these or any other side effect.
- **Diarrhea:** Loperamide (Imodium®) is available over the counter. You can take 2 tablets after the first episode of diarrhea, followed by 1 tablet (2mg) after each loose stool as needed. Do not take more than 8 tablets (16mg) in a 24-hour period. Call the clinic if this does not provide relief within 24 hours.
- **Constipation:** To help prevent constipation, add high fiber foods such as fruits, vegetables, and whole grains to your diet and, if possible, keep moving throughout the day. If you do not move your bowels in 2-3 days, you will need to take a laxative such as Senna-S, which is available over the counter. If not better in 2 days, call the clinic.
- **Mouth care** is very important. To prevent mouth sores, rinse your mouth with a mixture of ½ teaspoon of baking soda in 8 ounces of water after every meal

and at bedtime. Brush your teeth and gums often with a soft toothbrush. Do not use alcohol, mouthwashes that contain alcohol, or tobacco products

- **Skin care:** Use a sunblock with SPF 30 or higher that protects against both UVA and UVB rays when you are outdoors, even if it is just for a short time. Wear sunglasses and protective clothes (brimmed hat, long sleeves, etc.) when in the sun. Do not use tanning beds. If you develop a rash, keep the area clean and dry and check with your doctor before using any creams or ointments on the area.
- **Sleep problems, depression:** Talk to your doctor if you have problems sleeping or depression.
- **Birth defects:** If you have a female partner who could become pregnant, you must use effective contraception during treatment and for 2 weeks after your last dose. This drug may cause harm to a fetus.
- Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your response to relugolix.
- Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking relugolix.

When Should I Call the Doctor?

Call 911 or go to the nearest hospital emergency department if you have life-threatening symptoms such as:

- signs of severe allergic reaction: Swelling or tingling in your face, tongue, mouth, or throat; chest tightness; wheezing; trouble breathing or swallowing; dizziness, shortness of breath; heart palpitations; or hives
- dizziness; fainting; heart racing; or chest pain
- chest pain or pressure; or pain in arms, back, neck, or jaw
- sudden numbness or weakness of face, arm, or leg (especially on one side of the body); sudden confusion; trouble speaking or understanding; sudden trouble seeing in one or both eyes; or sudden trouble walking, dizziness, loss of balance or coordination

Please let us know if you go to the emergency room or are admitted to the hospital.

Call the doctor immediately if you have:

- any sign of infection: Fever of **100.4°F (38°C)** or higher, chills, cough, sore throat, pain or burning upon urination; redness or tenderness along a vein, at an IV site, or at any other skin wound