

Relugolix (Orgovyx[™])

Pronounced: rel-ue-GOE-lix

Classification: Gonadotropin-releasing hormone receptor antagonist/Anti-androgen

About Relugolix (Orgovyx[™])

Relugolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist. This blocks some of the hormones that can promote cancer growth from working. Most prostate cancers need the male hormone testosterone to grow. Testosterone is an androgen (type of hormone) produced by the testes and adrenal glands. Anti-androgen therapies work by blocking an enzyme necessary for the production of testosterone. Without testosterone, the cancer cells may either grow more slowly, or stop growing altogether.

How to take Relugolix

This medication comes in a tablet form to be taken by mouth, with or without food. It should be taken around the same time every day. You should not crush or chew the tablet, rather you should swallow it whole. If you are having trouble taking your medication speak to your pharmacist. If you miss a dose by less than 12 hours you should take the missed dose and then resume your normal schedule.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed. There is a different dose on the first day you take the medication which serves as a loading dose and if you stop therapy for longer than 7 days, it is recommended you re-load with the higher dose again.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: apalutamide, carbamazepine, fosphenytoin, phenobarbital, phenytoin, rifampin, amiodarone, azithromycin, carvedilol, clarithromycin, daclatasvir, dronedarone, erythromycin, itraconazole, ketoconazole, quinidine, quinine, ranolazine, ritonavir, and verapamil, among others. Be sure to tell your healthcare provider about all medications and supplements you take. Depending on the medications that you take, you may need to change the schedule or dosages of your medications due to their interactions or change one of the therapies. Ask to speak to your provider or pharmacist about any changes that need to be made.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced

by your prescription drug coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources if they are available.

Possible Side Effects

There are a number of things you can do to manage the side effects of relugolix. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Hot Flashes

There are a few things you can do to help with hot flashes. Several medications have been shown to help with symptoms, including clonidine (a blood pressure medication), low doses of certain antidepressants (such as venlafaxine and fluoxetine), and gabapentin. Talk to your healthcare team about these prescription products to determine if they are right for you.

Non-medical recommendations include:

- Keep well-hydrated with eight glasses of water daily.
- Drink ice water or apply an ice pack at the onset of a hot flash.
- Wear cotton or lightweight, breathable fabrics and dress in layers so you can adjust as needed.
- Exercise on a regular basis.
- Try practicing meditation or relaxation exercises to manage stress, which can be a trigger.
- Avoid triggers such as warm rooms, spicy foods, caffeinated beverages, and alcohol.

High Blood Sugar

This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

High Cholesterol

This medication can cause high cholesterol. Your cholesterol may be monitored using blood tests. Your provider may also suggest changes to your diet if you are affected by high cholesterol.

Muscle or Joint Pain/Aches

Your healthcare provider can recommend medications and other strategies to help relieve pain.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing, or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Liver Toxicity

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Less common, but important side effects can include:

• *Heart Issues:* This medication can cause QT prolongation, worsening congestive heart failure and changes to your electrolytes with can cause heart arrhythmias. Tell your provider if you are having any palpitations, feel as though your heartbeat is irregular, chest pain, or dizziness. Your heart may be monitored using electrocardiograms and your electrolytes may be monitored using blood tests.

Sexual and Reproductive Changes

This drug can affect your reproductive system, resulting in sperm production becoming irregular or stopping permanently. In addition, you may experience erectile dysfunction or a decreased desire for sex during treatment. Talk to your urologist about options for treating erectile dysfunction.

Exposure of an unborn child to this medication could cause birth defects, so you should not father a child while on this medication or for 2 weeks after your last dose. Effective birth control is necessary during treatment, even if you believe you are not producing sperm. You may want to consider sperm banking if you may wish to have a child in the future. Discuss these options with your oncology team.

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