

PATIENT INFORMATION

ORGOVYX (or-GO-vix)
(relugolix)
tablets

What is ORGOVYX?

ORGOVYX is a prescription medicine used in adults for the treatment of advanced prostate cancer.

It is not known if ORGOVYX is safe or effective in females.

It is not known if ORGOVYX is safe or effective in children.

Do not take ORGOVYX if you have had a severe allergic reaction to relugolix or any of the ingredients in ORGOVYX. See the end of this Patient Information for a complete list of the ingredients in ORGOVYX.

Before taking ORGOVYX, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including a condition called long QT syndrome.
- are pregnant or plan to become pregnant. ORGOVYX can harm your unborn baby and cause loss of pregnancy (miscarriage).
- have a partner who is pregnant or may become pregnant.
 - Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with ORGOVYX and for 2 weeks after the last dose of ORGOVYX.
- are breastfeeding or plan to breastfeed. It is not known if ORGOVYX passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking ORGOVYX with certain other medicines can affect how ORGOVYX works or may cause side effects.

You should not start or stop any medicine before you talk with your healthcare provider who prescribed ORGOVYX. Know the medicines you take. Keep a list of them with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ORGOVYX?

- Take ORGOVYX exactly as your healthcare provider tells you.
- Take 3 ORGOVYX tablets on your first day of treatment. After that, take 1 ORGOVYX tablet each day.
- Take ORGOVYX at about the same time each day.
- Take ORGOVYX with or without food.
- Swallow ORGOVYX tablets whole. Do not crush or chew tablets.
- Your healthcare provider may change your dose if needed.
- **Do not change your dose or stop taking ORGOVYX without talking with your healthcare provider first.**
- If you miss a dose of ORGOVYX, take it as soon as you remember. If the dose was missed by more than 12 hours, the missed dose should not be taken. Take your next dose at your regular time the next day.

What are the possible side effects of ORGOVYX?

ORGOVYX may cause serious side effects, including:

- **Changes in the electrical activity of your heart (QT prolongation).** Your healthcare provider may check your body salts (electrolytes) and the electrical activity of your heart during treatment with ORGOVYX. Tell your healthcare provider right away if you get any signs or symptoms of QT prolongation, including:
 - dizziness
 - feeling that your heart is pounding or racing (palpitations)
 - fainting
 - chest pain
- **Allergic reactions.** Stop taking ORGOVYX and tell your healthcare provider or get emergency medical help right away if you get any signs or symptoms of an allergic reaction, including:
 - swelling of your face, lips, tongue, throat, or trouble swallowing
 - trouble breathing
 - hives (raised bumps), rash, or redness all over your body

The most common side effects of ORGOVYX include:

- hot flushes
- increased blood sugar levels
- increased blood fat (triglyceride) levels
- muscle and joint pain
- decreased blood hemoglobin levels
- increased liver enzymes
- tiredness
- constipation
- diarrhea

Other side effects include weight gain, decreased sex drive, and erectile function problems.

ORGOVYX may cause fertility problems in males, which may affect your ability to father children. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of ORGOVYX.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ORGOVYX?

- Store ORGOVYX at room temperature. Do not store ORGOVYX above 86°F (30°C).
- Keep the bottle tightly closed after you first open it.
- The ORGOVYX bottle contains a desiccant to help keep your medicine dry (protect it from moisture). Do not remove the desiccant from the bottle.
- Dispose of unused medicines through community take-back disposal programs when available. If no community take-back disposal program is available go to www.fda.gov/drugdisposal for information on how to dispose of ORGOVYX the right way.
- **Do not** flush ORGOVYX down the toilet.

Keep ORGOVYX and all medicines out of the reach of children.

General information about the safe and effective use of ORGOVYX.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ORGOVYX for a condition for which it was not prescribed. Do not give ORGOVYX to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ORGOVYX that is written for health professionals.

What are the ingredients in ORGOVYX?

Active ingredient: relugolix

Inactive ingredients: mannitol, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide, ferric oxide red, and carnauba wax.

Manufactured for: Sumitomo Pharma America, Inc., Marlborough, MA 01752

For more information, go to www.orgovyx.com or call 1-833-696-8268.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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