

ORAL CHEMOTHERAPY EDUCATION



RELUGOLIX

Name of your medication

Generic name — relugolix (reh-loo-GOH-lix)

Brand name — Orgovyx® (or-GOH-vix)

Approved uses

Relugolix is used for the treatment of adult patients with prostate cancer.

Dose and schedule

Taking relugolix as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of relugolix is a loading dose of 360 mg (three tablets) on the first day of treatment followed by 120 mg (one tablet) taken orally once daily, at approximately the same time each day.
- Your dose is based on many factors, including your overall health and diagnosis.
- Relugolix can be taken with or without food, but should be taken at the same time each day.
- Relugolix should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow relugolix, talk to your care provider or pharmacist for possible options.
- If you miss a dose of relugolix,
 - Only take the missed dose if it has been less than 12 hours since you were supposed to take it. Then, take the next dose at the regularly scheduled time.
 - Do not take two doses at one time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.
- Do not take an additional dose if vomiting occurs after taking relugolix. Instead, continue with your next scheduled dose the following day.

Drug and food interactions

- Relugolix has many drug interactions. Please inform your care provider of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle relugolix with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store relugolix at room temperature (68°F–77°F) in a dry location away from light. Do not store relugolix above 86°F (30°C).
- Relugolix comes with a desiccant packet in the bottle to protect your medicine from moisture. Do not remove the desiccant packet from the bottle.
- Keep relugolix out of reach of children and pets.
- Leave relugolix in the provided packaging until it is ready to be taken.

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- Whenever possible, you should give relugolix to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the relugolix to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the relugolix from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is not recommended to be used with relugolix.
- If you have any unused relugolix, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of relugolix.
- If you are traveling, put your relugolix's packaging in a separate sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Relugolix

Below are common side effects that have been known to happen in about one-third or more of patients taking relugolix are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Hot flashes (sudden sweating and feelings of warmth)</p>	<p>If hot flashes are bothersome:</p> <ul style="list-style-type: none"> Mild, regular exercise program may help. Consult first with your care provider. Try staying in a cool environment. Wear layers so that you can remove outer layers when experiencing a hot flash. Avoid or limit caffeine, spicy food, alcohol, and stress, which may worsen hot flashes. <p>Inform your care provider if your hot flashes are bothersome as there may be medications that can help.</p>
<p>Muscle or joint pain or weakness</p>	<ul style="list-style-type: none"> Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Stay as active as possible, but know that it is OK to rest as needed, too. Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
<p>Fatigue</p>	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> Stay as active as possible, but know it is OK to rest as needed. Try to do some activity every day. Plan your activities, and do them at a time of day when you feel a bit more energetic. Avoid operating heavy machinery if you feel too tired.
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> High glucose (blood sugar) levels High triglyceride (blood fat) levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> Shortness of breath Chest discomfort Weakness or fatigue New aches and pains Headaches Dizziness Swelling of your legs or feet

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Serious side effects of relugolix

- Relugolix may cause rare but serious side effects, including the following:
 - 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. Tell your healthcare provider right away if you get any signs or symptoms of QT prolongation, including dizziness, fainting, the feeling that your heart is pounding or racing (palpitations), and chest pain.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since relugolix remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take relugolix, it is important to follow the instructions below every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or relugolix with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Relugolix may cause fertility problems in men, which may affect your ability to father children. Talk to your healthcare provider if this is a concern for you.
- Men should not get a partner pregnant while taking relugolix.
- Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 2 weeks after the last dose of relugolix.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.

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- ❑ It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- ❑ Talk with your care provider about the process for obtaining your relugolix.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.orgovyx.com

Product prescribing information: www.accessdata.fda.gov/drugsatfda_docs/label/2020/214621s000lbl.pdf

Product resources: www.orgovyx.com/support-and-resources

Updated – June 22, 2021

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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