

For the Patient: Relugolix
Other names: ORGOVYX®

- Relugolix (rel" ue goe' lix) is a drug that is used to treat prostate cancer. Relugolix decreases testosterone (a male sex hormone). It is a tablet that you take by mouth.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to relugolix before taking relugolix.
- It is important to **take** relugolix exactly as directed by your doctor. Make sure you understand the directions.
- You may **take** relugolix with food or on an empty stomach. Your dose may be taken at any time of the day but should be taken about the same time each day.
- If you miss a dose of relugolix, take it as soon as you can if it is within 12 hours of
  the missed dose. If it is more than 12 hours since your missed dose, skip the missed
  dose and go back to your usual dosing times. Do NOT take more than one dose to
  make up for the missed dose. Call your healthcare team for advice if you miss more
  than one dose.
- Other drugs such as azithromycin (ZITHROMAX®) and rifampin (ROFACT®) may interact with relugolix. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of relugolix.
- Relugolix may affect fertility in men. If you plan to have children, discuss this with your doctor before being treated with relugolix.
- Relugolix may damage sperm and may harm the baby if used during pregnancy. It is
  best to use birth control while being treated with relugolix and for 2 weeks after
  your treatment has ended. It is best for male patients to use barrier protection (e.g.,
  condom) during sexual activity with a pregnant woman. Tell your doctor right away if
  your partner becomes pregnant.
- **Store** relugolix tablets out of the reach of children, at room temperature, away from heat, light, and moisture.

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Tell your doctor, dentist, and other health professionals that you are being treated with relugolix before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to

help manage the side effects are included.

| SIDE EFFECTS                                                                                                           | MANAGEMENT                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                        | WANAGEWENT                                                                                                                                                                                                                                                                                                                                                                                                         |
| Nausea does not usually occur with relugolix.                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Diarrhea</b> may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated. | <ul> <li>If diarrhea is a problem:</li> <li>Drink plenty of fluids.</li> <li>Eat and drink often in small amounts.</li> <li>Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.*</li> <li>Tell your healthcare team if you have diarrhea for more than 24 hours.</li> </ul>                                                                                                                |
| Constipation may sometimes occur.                                                                                      | <ul> <li>Exercise if you can.</li> <li>Drink plenty of fluids.</li> <li>Try the ideas in Food Choices to Manage<br/>Constipation.*</li> </ul>                                                                                                                                                                                                                                                                      |
| Abnormal heart rhythm (QT prolongation) rarely occurs.                                                                 | <ul> <li>Minimize your risk of abnormal heart rhythm by:</li> <li>always checking with your pharmacist or doctor about drug interactions when starting a new medication, herbal product, or supplement.</li> <li>Get emergency help <i>immediately</i> if your heart is beating irregularly or fast OR if you feel faint, lightheaded, or dizzy.</li> </ul>                                                        |
| High blood pressure may sometimes occur.                                                                               | <ul> <li>Your blood pressure may be checked by your healthcare team during your visit.</li> <li>You may be asked to check your blood pressure frequently between visits.</li> <li>Your doctor may give you a prescription for blood pressure medication if your blood pressure is high.</li> <li>Tell your doctor if you are already on blood pressure medication as they may need to adjust your dose.</li> </ul> |

| SIDE EFFECTS                                                                                                                                                | MANAGEMENT                                                                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hot flashes (sudden sweating and feelings of warmth) commonly occur.                                                                                        | If hot flashes are troublesome:                                                                                                                          |
|                                                                                                                                                             | Take your relugolix at bedtime.                                                                                                                          |
|                                                                                                                                                             | <ul> <li>If night sweats interfere with sleep, try taking relugolix in the morning.</li> <li>Some people find it helpful to avoid</li> </ul>             |
|                                                                                                                                                             | alcohol, spicy food, and caffeine (such as coffee, tea, colas, chocolate).                                                                               |
|                                                                                                                                                             | Follow a regular exercise program.                                                                                                                       |
|                                                                                                                                                             | Try staying in a cool environment.                                                                                                                       |
|                                                                                                                                                             | <ul> <li>Wear layers so that if you do experience<br/>a hot flash, the outer layers may be<br/>removed.</li> </ul>                                       |
|                                                                                                                                                             | Ask your healthcare team for advice if your hot flashes continue to bother you.                                                                          |
| Muscle, joint, bone or back pain may sometimes occur.                                                                                                       | You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. |
|                                                                                                                                                             | Tell your healthcare team if the pain interferes with your activity.                                                                                     |
| <b>Sugar control</b> may be affected in patients with diabetes.                                                                                             | Check your blood sugar regularly if you have diabetes.                                                                                                   |
| <b>Tiredness</b> and lack of energy may sometimes occur.                                                                                                    | <ul> <li>Do not drive a car or operate machinery<br/>if you are feeling tired.</li> </ul>                                                                |
|                                                                                                                                                             | Try the ideas in Fatigue/Tiredness – Patient Handout.*                                                                                                   |
| Hair loss does not occur with relugolix.                                                                                                                    |                                                                                                                                                          |
| <b>Decreased libido</b> (loss of sexual desire) may occur.                                                                                                  | This may return to normal when you stop taking relugolix.                                                                                                |
| Impotence (loss of sexual ability) may occur.                                                                                                               | This may return to normal when you stop taking relugolix.                                                                                                |
| Bone loss happens gradually and normally with age, but may happen more quickly with this medication. Over time, your risk of breaking a bone may be higher. | Refer to Prevention of Osteoporosis for<br>Men with Prostate Cancer on Hormone<br>Therapy* for more information.                                         |

Relugolix (interim handout)

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| SIDE EFFECTS                                                                          | MANAGEMENT                                                                                                                                                                                                                                                            |
|---------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Increase in triglycerides (one of the types of fat in the blood) may sometimes occur. | <ul> <li>Tell your doctor if you have:</li> <li>A history of heart disease.</li> <li>High blood pressure.</li> <li>High cholesterol or triglycerides.</li> <li>You may need to have your triglyceride level checked a few months after starting relugolix.</li> </ul> |

<sup>\*</sup>Please ask your nurse or pharmacist for a copy.

## STOP TAKING RELUGOLIX AND CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an allergic reaction (rare) soon after a treatment including difficulty swallowing or breathing, swelling of face or throat, dizziness, fast heartbeat, hives or rash.
- Signs of a stroke such as sudden onset of severe headache, eyesight changes, slurred speech, loss of coordination, weakness or numbness in arm or leg.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.

## CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower legs.

## CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Trouble sleeping.
- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Breast swelling or soreness.
- Increased sweating.
- Skin rash.
- Weight gain.
- Feelings of sadness that are not normal for you.
- For patients with diabetes: uncontrolled blood sugars.

## REPORT ADDITIONAL PROBLEMS TO YOUR HEALTHCARE TEAM

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