



## WHAT IS ORGOVYX® RELUGOLIX?

- A hormonal therapy drug used to treat some prostate cancers.
- Prescribed by your oncologist; can be renewed by your registered physician. Prescribed by your hospital specialist at least once per year.
- Available from community pharmacies on presentation of your prescription.




- Almond-shaped film-coated tablet, light red, **dosed at 120 mg** with “R” on one side and “120” on the other.



- Do not store above 25°C, and keep out of the sight and reach of children.
- Do not take the tablets out of the bottle to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- Do not throw away opened bottles, please return them to your pharmacist.

## HOW TO TAKE THIS MEDICINE

When?	.....	<b>= 1 dose per day at a set time With or without a meal</b>
How?		Swallow the tablet(s) whole, with water, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **medical diary**\* and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

*This leaflet is not a prescription, please refer to your most recent prescription.*

## IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- **If it has been less than 12 hours since your dose was due**, take the missed dose immediately. Take your next dose at the usual time. Keep a record in your medical diary\*.
- **If it has been more than 12 hours since your dose was due**, do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary\*.
- **If you throw up**, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary\*.

## INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with your doctor or pharmacist that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.











If you have sexual intercourse with a woman of child-bearing age, you and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 2 weeks after the last dose**.

Male fertility can be affected during treatment with relugolix.

\* Patient diary available (in French) at [www.omedit-fiches-cancer.fr](http://www.omedit-fiches-cancer.fr)

# WHAT SIDE EFFECTS CAN OCCUR WITH ORGOVYX® RELUGOLIX?

Like all medicines, relugolix may cause side effects, although not everybody gets them.

Side effects	Prevention
 Rash	Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.
 Digestive effects: constipation, diarrhoea, nausea	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). <b>In case of constipation</b> , eat foods rich in fibre (bran, grains, wholemeal bread, green vegetables, fruit and nuts) and exercise regularly. <b>In case of diarrhoea</b> , eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). <b>In case of nausea</b> , divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.
 Low red blood cells	Contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches.
 Joint and muscle pain	Exercise regularly (suitable activities include walking and swimming). Warm up before exercising. Remember to hydrate before, during and after exerting yourself. Avoid repetitive movements and strenuous physical effort. Use a walking stick to support your joints.
 Insomnia, sleep disorders	Set regular times for getting up and going to bed, introduce a ritual (dim lighting, gentle music, reading). Sleep in a room that is 19°C. Get sufficient exercise in the day, but not in the evening. Limit alcohol, tobacco and caffeine consumption, particularly in the evening. Avoid heavy evening meals.
 Hot flashes	Cool down with a mister; remember to hydrate. Wear cotton clothing; do not cover up too much. Avoid triggers (cigarettes, alcohol, hot or spicy food, stress).
 High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 6 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.
 Headache, tiredness, dizziness	Drink sufficient quantities (1.5 to 2 L water per day) and eat healthily, at regular intervals. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Rest during the day, while maintaining up to moderate levels of activity. Establish a sleep schedule; avoid going to bed and getting up late. Take care when driving.



Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.

You can also ask your [Regional Pharmacovigilance Centre](#) and report any side effects online: [signalement-sante-gouv-fr](#)



Remember to go for the lab tests prescribed by your doctor.

## WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Useful contacts:

**Contact your doctor rapidly** in case of:

- Extreme tiredness, shortness of breath, paleness
- Chest pain or tightness, arm pain, shortness of breath, irregular heartbeat
- Migraine or severe headache
- Any persistent or worsening side effect



Note: