

ORGOVYX[®] ▼
(relugolix) 120 mg
tablets

accord 
Oncology &
Haematology



Your guide to

ORGOVYX[®] ▼ (relugolix)

You have been given this guide because you have been prescribed ORGOVYX[®] and live in the United Kingdom (UK). Please read the Patient Information Leaflet before starting your medication.

This guide has been produced by Accord-UK Ltd.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [yellowcard.mhra.gov.uk](https://www.yellowcard.mhra.gov.uk). By reporting side effects, you can help provide more information on the safety of this medicine. Adverse events should also be reported to Accord-UK Ltd Medical Information on 01271 385257.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. See [yellowcard.mhra.gov.uk](https://www.yellowcard.mhra.gov.uk) for how to report side effects.



Your doctor has prescribed you ORGOVYX®.

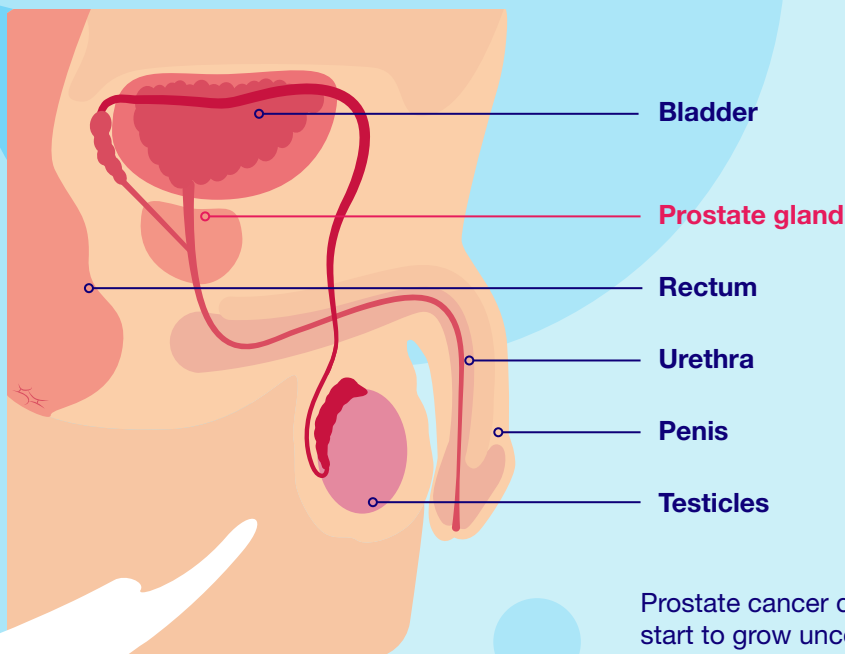
- **Keep this guide. You may need to read it again**
 - **This guide is only given to UK patients with advanced prostate cancer who respond to hormone therapy, as well as prior to or in combination with radiotherapy in the treatment of high-risk localised and locally advanced prostate cancer who have been prescribed ORGOVYX®**
 - **The information in this guide does not replace the information in the ORGOVYX® Patient Information Leaflet**
 - **If you have any further questions, please ask your doctor, pharmacist or nurse**
 - **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours**
 - **If you experience any side effects, please talk to your doctor, pharmacist or nurse OR report directly via the national reporting system, as described on the front page of this guide. This includes any possible side effects not listed in this guide (see section: 'How can I manage the side effects?' on page 14)**
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Contents

What is prostate cancer?	04
What are the symptoms of prostate cancer?	05
What is ORGOVYX®?	06
How does ORGOVYX® work?	07
How do I take ORGOVYX®?	08
What happens if I miss a dose?	09
Safety information	10
What side effects might I experience?	12
How can I manage the side effects?	14
Frequently asked questions	16
Notes	18

What is prostate cancer?

The prostate is a walnut-sized gland that sits at the base of your bladder. It helps to produce semen, making it an important part of reproduction.^{1,2}



Adapted from: Cancer Research UK (2019).¹

Prostate cancer develops when cells in the prostate start to grow uncontrollably; this is due to the growth of abnormal cells that do not behave like normal cells.^{2,3}

These cancer cells can mutate and multiply to create more cancer cells, causing the cancer to grow. The uncontrolled growth means the cancer cells crowd out and overpower the normal cells. Sometimes the cancer cells may spread to other parts of the body; this is known as metastasis.³

While the causes of prostate cancer are not known, several risk factors for developing prostate cancer have been identified, including increasing age, ethnicity, family history of prostate cancer and certain gene mutations.⁴

Prostate cancer is a cancer that forms in the cells of the prostate gland.¹

What are the symptoms of prostate cancer?

Possible symptoms of prostate cancer include:^{2,4-6}

Increased urination, especially at night

Burning or pain while urinating

Trouble holding urine

Urgent urination

Feeling like the bladder has not emptied fully

Difficulty starting to urinate, including straining

Erectile dysfunction

Blood in the urine or semen

Weak, dribbling or interrupted urine flow

If the prostate cancer has spread to other parts of the body, it can cause other symptoms, such as pain or stiffness in the bones, lower back, hips or pelvis, unintentional weight loss and pain in the testicles.^{5,6}

You should see your doctor if you experience any of the above symptoms. However, it is important to remember that these symptoms can be common in people who do not have prostate cancer and they may also be caused by other conditions. For example, enlargement of the prostate can press on the urethra and, whilst it does not usually develop into cancer, can result in similar symptoms to prostate cancer.⁴

What is ORGOVYX®?

ORGOVYX® is a prescription-only medicine that contains the active substance relugolix. It is used for the treatment of adult patients with advanced prostate cancer who respond to hormone therapy, as well as prior to or in combination with radiotherapy in the treatment of high-risk localised and locally advanced prostate cancer.⁷



What does ORGOVYX® look like?

ORGOVYX® is available as an oral tablet containing 120 mg of relugolix. It is a light red, almond-shaped, film-coated tablet inscribed with “R” on one side and “120” on the other side.⁷



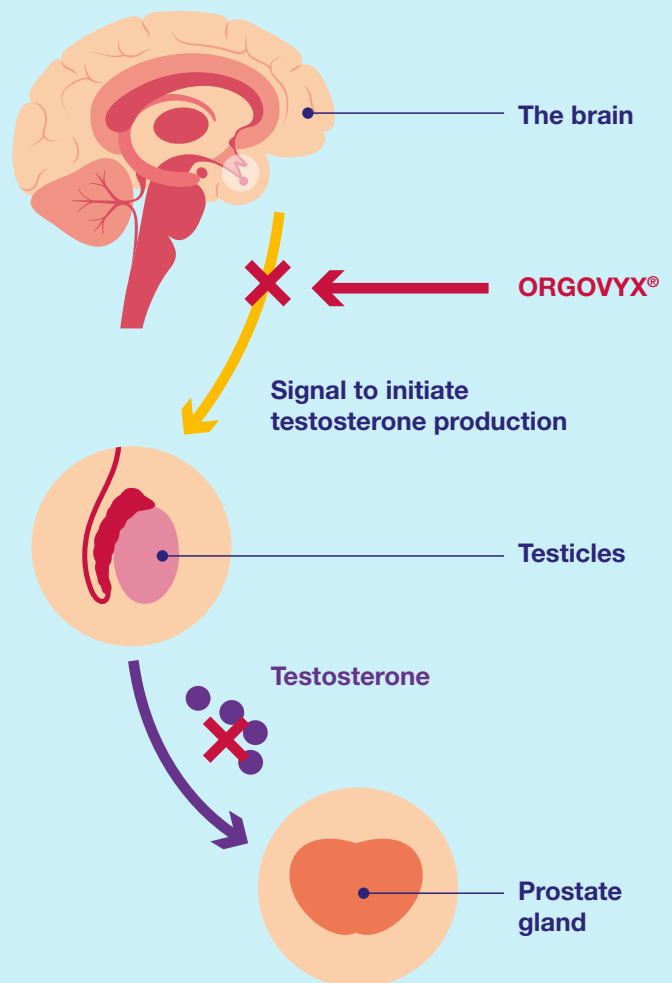
ORGOVYX® comes in a white plastic bottle containing 30 film-coated tablets. Each bottle has an induction-sealed, child-resistant cap and contains a desiccant that helps keep your tablets dry and protects them from moisture. The desiccant should not be removed or consumed.⁷

How does ORGOVYX® work?

Hormones are chemicals produced in the body.⁸⁻¹⁰ Testosterone is the male sex hormone responsible for controlling the growth and development of the prostate. It also controls other male characteristics, such as muscle strength.⁹

ORGOVYX® is a type of hormone therapy containing relugolix. Relugolix works by blocking a step in the process that signals the testes to produce testosterone. As testosterone can stimulate the growth of prostate cancer, relugolix prevents prostate cancer cells from growing and dividing by decreasing testosterone to very low levels.⁷

Whilst hormone therapy alone does not cure prostate cancer, it can be used to slow the progression of advanced prostate cancer and help relieve or manage symptoms.^{8,9}



As ORGOVYX® is a hormone therapy, you will have regular check-ups with your doctor during treatment.¹¹

How do I take ORGOVYX®?

Treatment with ORGOVYX® should be started by and supervised by a doctor experienced in the medical treatment of prostate cancer. It is important to take ORGOVYX® exactly as your doctor has told you. If you are unsure, please check with your doctor or pharmacist.^{7,12}

The recommended dose of ORGOVYX® is:⁷

- Three tablets on the first day of treatment
- One tablet once a day after that, taken around the same time each day

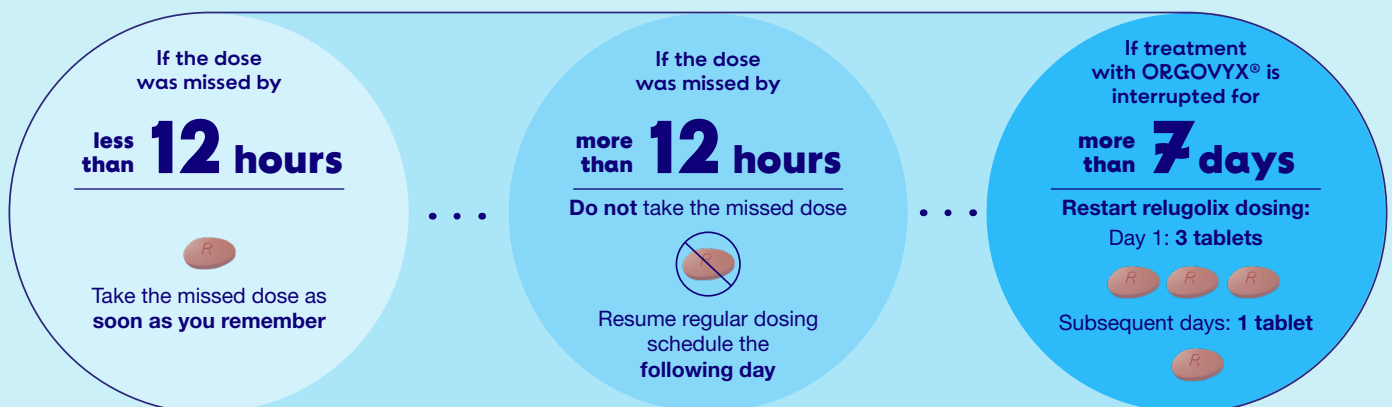


Things to remember whilst taking ORGOVYX®:⁷

- ORGOVYX® is taken orally and you should **swallow the whole tablet** – do not crush or chew your tablets
- You can take your tablets **with or without food** and with some liquid
- Take ORGOVYX® **exactly** how your doctor prescribed
- **Do not stop treatment or change your prescribed dose** of ORGOVYX® without talking to your doctor or pharmacist first

What happens if I miss a dose?

- If a dose is missed by **less than 12 hours** after the usual time you would have taken it, take it as soon as you remember, and then carry on taking your next tablets thereafter as usual⁷
- If you miss a dose by **more than 12 hours**, do not take the dose. Take your next dose the following day as usual⁷
- If treatment with ORGOVYX® is interrupted for **more than 7 days**, you should speak to your doctor. ORGOVYX® must be restarted with three tablets on the first day, followed thereafter by one tablet once daily¹²



If you would like to stop taking ORGOVYX®, talk to your doctor first. Your doctor will explain the effects of stopping treatment, discuss other possibilities with you and be able to answer any further questions you may have.⁷

Safety information

Before taking ORGOVYX®, you should talk to your doctor or pharmacist if you have any of the following:⁷

- Heart circulation conditions such as heart rhythm problems (arrhythmia)
- If you get any signs or symptoms like dizziness, fainting, feeling that your heart is pounding or racing (palpitations) or chest pain; these can be symptoms of serious heart rhythm problems
- Liver disease
- Kidney disease
- Osteoporosis or any condition that affects the strength of your bones

You should also monitor your disease with a blood test for prostate-specific antigen (PSA).

Contraindications

You should not take ORGOVYX® if you are allergic to the substance relugolix or any of the following ingredients in this medicine:¹²

- Mannitol (E421)
- Sodium starch glycolate (E468)
- Hydroxypropyl cellulose (E463)
- Magnesium stearate (E572)
- Hypromellose (E464)
- Titanium dioxide (E171)
- Iron oxide red (E172)
- Carnauba wax (E903)





Interaction with other medications

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.⁷

- ORGOVYX® may interfere with some medicines used to treat heart rhythm problems or may increase the risk of heart rhythm problems when used with some other drugs⁷
- Other medicinal products may interfere with the absorption of relugolix. This could increase the levels of ORGOVYX® in the blood, which may increase the likelihood of experiencing side effects. Alternatively, some medicines may decrease the levels of ORGOVYX® in the blood and reduce its effectiveness⁷

Fertility

ORGOVYX® is intended for use in men with prostate cancer. Please be aware that:⁷

- ORGOVYX® could have an effect on male fertility
- If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method used by your partner during treatment and for 2 weeks after treatment with this medicine, to prevent pregnancy
- If you are having sex with a pregnant woman, you should use a condom to protect the unborn child

Driving and operating machinery

ORGOVYX® has no or little influence on your ability to drive and use machines, but you may experience dizziness or tiredness.¹² These are common (dizziness) and very common (tiredness) side effects, related to the treatment or from the effects of the disease, that may influence your ability to drive and use machines.⁷

What side effects might I experience?

Like most medications, this medication may have some potential side effects that impact your life – although not everybody experiences them. It is important to understand the possible side effects when starting treatment.⁷

Blocking or taking away testosterone with hormone therapy can help control the cancer and delay or manage any symptoms. However, as testosterone also plays an important role in male health and development, alterations to its levels may cause other things in your body to change too.¹¹

Very commonly observed side effects during ORGOVYX® therapy include:⁷

Tiredness | **Hot flushes**

Muscle and joint pain

Diarrhoea | **Constipation**

Commonly observed side effects during ORGOVYX® therapy include:⁷

Sleeplessness | **Depression** | **Headache**

Breast enlargement in men (gynaecomastia)

Dizziness | **Increased sweating** | **Rash**

Low red cell count (anaemia) | **Increased weight**

Increased blood cholesterol level | **Increased blood sugar levels**

High blood pressure | **Decreased interest in sex**

Upset stomach including feeling sick (nausea) | **Increased blood fat (triglyceride) levels**





You should talk to your doctor, pharmacist or nurse if you experience any side effects that bother you or do not go away.



Please refer to the Patient Information Leaflet that came with your medicine for a more comprehensive list of possible side effects.⁷

You may find your side effects improve or become easier to manage over time. The side effects of hormone therapy will likely last as long as you are on hormone therapy.¹¹

How can I manage the side effects?

To help you manage any side effects experienced as a result of your hormone therapy, it is important to speak with your doctor who will advise you on any appropriate treatments available to you. In addition to the very common side effects listed on page 12, other side effects may be experienced and managed:¹¹

Hot flushes

Hot flushes can vary from feeling overheated for a few moments to a few hours of sweating. You may not need treatment if your hot flushes are mild or don't bother you. However, if you find hot flushes are disrupting your everyday life, there are steps you can take to help. Making lifestyle changes, such as maintaining a healthy weight and wearing cotton clothes, especially at night, may help you to manage your hot flushes. Additionally, your doctor may suggest medications that could help relieve the symptoms of hot flushes and reduce how often you get them. Your hot flushes may also be relieved by complementary therapies like acupuncture, hypnotherapy, cognitive behavioural therapy and herbal remedies.

Fatigue

Hormone therapy may cause extreme tiredness, known as fatigue. Fatigue can impact everyday life, by affecting your energy levels, motivation and emotions. Changes to your lifestyle, such as being physically active, eating a well-balanced diet and planning activities for when you know you'll have the most energy can help combat fatigue.

Changes to your sex life

Hormone therapy can affect your sex life in different ways and in most cases will last for the duration you are on hormone therapy. It isn't always easy to talk about sex and relationships but being open with your partner about your thoughts and feelings may help you feel more connected and more confident in facing any challenges.

Weight gain

It is possible for hormone therapy to impact your weight. This can be especially challenging but making small lifestyle changes can help make a difference. Being physically active and having a well-balanced diet is key to leading a healthy lifestyle. However, if you are finding losing weight particularly hard, you could consult a dietician or join a local weight loss group.





Bone thinning

Testosterone helps to keep bones strong. Over time, long-term hormone therapy may cause your bones to lose their bulk. Severe bone thinning can lead to a condition known as osteoporosis, which increases your risk of broken bones. To reduce your risk of bone thinning and osteoporosis, you should ensure your diet is rich in calcium and vitamin D, whilst maintaining a healthy weight and an active lifestyle. There are also medications that can treat osteoporosis caused by hormone therapy.

Strength and muscle loss

Hormone therapy can cause a decrease in muscle tissue and an increase in body fat. This may change the way your body looks and how physically strong you feel. Regular gentle resistance exercise, such as lifting light weights or using resistance bands, may help to prevent muscle loss and keep muscles strong. Additionally, your doctor may be able to refer you to a physiotherapist, recommend a local exercise program or give you some gentle exercises to complete at home.

Changes to your memory and concentration

You may find it harder than usual to concentrate or focus on certain tasks whilst you are having hormone therapy. Steps you can take to help improve your focus include keeping lists or setting reminders, getting plenty of rest and eating a well-balanced diet. It can also help to focus on one task at a time.

Low moods

Hormone therapy can affect your mood and you may feel more emotional than usual. It's important to go easy on yourself and remember these feelings are normal. You may find it helpful to be open about the way you're feeling, whether this is with friends or family or with a counsellor. If you don't find your mood improves, there are medications that can be prescribed by your doctor to help.

Frequently asked questions

How can I safely dispose of ORGOVYX®?

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.⁷

What should I do if I would like to stop taking ORGOVYX®?

If you would like to stop taking this medicine, talk to your doctor or pharmacist first. Your doctor or pharmacist will explain the effects of stopping treatment and discuss other possibilities with you.⁷

How should I store ORGOVYX®?

ORGOVYX® does not require any special storage conditions. However, you should ensure it is kept out of the sight and reach of children.⁷

Where can I find the expiry date of my ORGOVYX® tablets?

The expiry date is stated on the outer carton and on the bottle label after 'EXP'. The expiry date refers to the last day of that month and year. You should not use ORGOVYX® after the expiry date.⁷

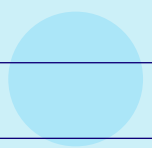
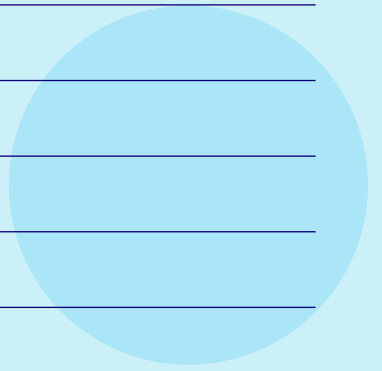
What should I do if I have taken more ORGOVYX® than recommended?

If you have taken too many ORGOVYX® tablets or discover that a child has taken some, talk to your doctor as soon as possible. Bring the medicine to show the doctor.⁷



**For any further questions,
please consult your doctor,
pharmacist, or nurse, or visit
www.orgovyx.co.uk/patients/
for more information.**

Notes



References:

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8. Cancer Research UK. 2023. The hormone system and cancer. Available from: <https://www.cancerresearchuk.org/what-is-cancer/body-systems-and-cancer/the-hormone-system-and-cancer> (Accessed January 2025).
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10. Prostate Cancer UK. 2022. Hormone therapy. Available from: <https://prostatecanceruk.org/prostate-information-and-support/treatments/hormone-therapy> (Accessed January 2025).
11. Prostate Cancer UK. 2022. How hormone therapy affects you. Available from: <https://prostatecanceruk.org/prostate-information/living-with-prostate-cancer/how-hormone-therapy-affects-you> (Accessed January 2025).
12. ORGOVYX[®] Summary of Product Characteristics.

PSA, prostate-specific antigen; UK, United Kingdom.