

Orgovyx® 120 mg film-coated tablets

(relugolix)

UK5301846P99-A2.0

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This product is called Orgovyx 120 mg film-coated tablets but will be referred to as Orgovyx throughout the leaflet.

What is in this leaflet

1. What Orgovyx is and what it is used for
2. What you need to know before you take Orgovyx
3. How to take Orgovyx
4. Possible side effects
5. How to store Orgovyx
6. Contents of the pack and other information

1. What Orgovyx is and what it is used for

Orgovyx 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.

Relugolix works by blocking a step in the process that signals the testes to produce testosterone (the male sex hormone). As testosterone can stimulate the growth of prostate cancer, by decreasing it to very low levels, relugolix prevents prostate cancer cells from growing and dividing.

2. What you need to know before you take Orgovyx

Do not take Orgovyx

- if you are allergic to relugolix or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Orgovyx if you

have any of the following:

- Heart circulation conditions such as heart rhythm problems (arrhythmia). The risk of heart rhythm problems may be increased when using Orgovyx. Your doctor may check your body salts (electrolytes) and the electrical activity of your heart during treatment with Orgovyx.
- Tell your doctor right away if you get any signs or symptoms like dizziness, fainting, feeling that your heart is pounding or racing (palpitations) or chest pain. Those can be symptoms of serious heart rhythm problems.
- Liver disease. Liver function may need to be monitored. Use of Orgovyx has not been investigated in patients with severe liver disease.
- Renal (kidney) disease.
- Osteoporosis or any condition that affects the strength of your bones. Reduced levels of testosterone may lead to thinning of bones.
- Monitoring of your disease with a blood test for prostate-specific antigen (PSA).

Children and adolescents

Orgovyx is not for use in children and adolescents under 18 years of age.

Other medicines and Orgovyx

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

Orgovyx may interfere with some medicines used to treat heart rhythm problems (e.g. quinidine, procainamide, amiodarone and sotalol) or might increase the risk of heart rhythm problems when used with some other drugs (e.g. methadone [used for pain relief and part of drug addiction detoxification], moxifloxacin [an antibiotic], antipsychotics used for serious mental illnesses).

Other medicines may interfere with the absorption of relugolix, resulting in either an increase in blood levels that may increase side effects or decrease in blood levels that may decrease the effectiveness of Orgovyx. Examples of medicines that may interfere with Orgovyx include:

- Certain medicines used to treat **epilepsy** (e.g. carbamazepine, phenytoin, phenobarbital).
- Certain medicines used to treat **bacterial infections** (e.g. rifampicin, azithromycin, erythromycin, clarithromycin, gentamicin, tetracycline).
- Certain medicines used to treat **fungal infections** (e.g. ketoconazole, itraconazole).
- Certain medicines used to treat **prostate cancer** (e.g. apalutamide).
- Herbal remedies containing **St John's Wort** (*Hypericum perforatum*).
- Certain medicines used to treat **high blood pressure**

(e.g. carvedilol, verapamil).

- Certain medicines used to treat **arrhythmias** (e.g. amiodarone, dronedarone, propafenone, quinidine).
- Certain medicines used to treat **angina** (e.g. ranolazine).
- Certain medicines used as **immunosuppressants** (e.g. cyclosporine).
- Certain medicines used to treat **HIV infections** (e.g. ritonavir [or ritonavir-containing combinations], efavirenz).
- Certain medicines used to treat **hepatitis C** (e.g. telaprevir).

Your doctor may therefore change your medications, change when you take certain medications, the dose of the medicines, or increase the dose of Orgovyx.

Pregnancy, breast-feeding, and fertility

Orgovyx is intended for use in men with prostate cancer. This medicine could possibly have an effect on male fertility. This medicine is not indicated in women who could become pregnant. It is not used in women who are, or may be pregnant or breast-feeding.

• Information for men:

- 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, use a condom to protect the unborn child.

Driving and using machines

Tiredness (very common) and dizziness (common) side effects (see section 4) may impair your ability to drive and use machines. These side effects may be due to the treatment or effects resulting from the underlying disease.

Orgovyx contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Orgovyx

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- three tablets on the first day of treatment.
- one tablet once a day after that, taken around the same time each day.

Your doctor may change your dose if needed.

Swallow whole. The tablets can be taken with or without food with some liquid.

If you take more Orgovyx than you should

There have been no reports of serious harmful effects from taking several doses of this medicine at once. If you have taken too many Orgovyx tablets, or you discover that a child has taken some, talk to your doctor as soon as possible. Bring the medicine to show the doctor.

If you forget to take Orgovyx

If you remember missing a dose 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 at the next days as usual. If you miss a dose by more than 12 hours, do not take the dose. Just take your next dose the following day as usual.

If you stop taking Orgovyx

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious.

Seek urgent medical attention if you develop:

- Rapid swelling of your face, mouth, lips, tongue, throat, abdomen, or arms and legs (angioedema) (uncommon: may affect up to 1 in 100 people).

The following side effects have been reported with Orgovyx and are listed below according to the frequency with which they occur.

Very common (may affect more than 1 in 10 people):

- hot flush
- diarrhoea
- constipation
- muscle and joint pain
- tiredness

Common (may affect up to 1 in 10 people):

- low red cell count (anaemia)
- breast enlargement in men (gynaecomastia)
- sleeplessness
- depression
- dizziness
- headache
- high blood pressure
- upset stomach including feeling sick (nausea)
- increased sweating
- rash
- decreased interest in sex
- increased weight

- increased blood sugar levels
- increased blood fat (triglyceride) levels
- increased blood cholesterol level

Uncommon (may affect up to 1 in 100 people):

- thinning of the bones (osteoporosis)
- increased liver enzymes
- hives (urticaria)

Rare (may affect up to 1 in 1,000 people):

- heart attack

Not known (frequency cannot be estimated from the available data):

- changes in the electrocardiogram (QT prolongation)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Orgovyx

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Orgovyx contains

- The active substance is relugolix.
- The other ingredients are mannitol (E421), sodium starch glycolate (E468), hydroxypropyl cellulose (E463), magnesium stearate (E572), hypromellose (E464), titanium dioxide (E171), iron oxide red (E172), carnauba wax (E903).

See "Orgovyx contains sodium" in section 2 for more information.

What Orgovyx looks like and contents of the pack

Orgovyx film-coated tablets are light red, almond-shaped, film-coated tablets (11 mm [length] × 8 mm [width]) with "R" on one side and "120" on the other side. Orgovyx is available in a plastic white bottle containing 30 film-coated tablets.

Orgovyx is available in a pack size of 30 film coated tablets. Each bottle also contains a desiccant to help to keep your medicine dry (protect it from moisture), do not remove the desiccant from the bottle. Each bottle is enclosed with an induction-sealed, child-resistant cap

Manufacturer

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For any information about this medicine, please contact the local representative of the Product Licence Holder:
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