



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/145519/2022  
EMA/H/C/005353

## Orgovyx (*relugolix*)

An overview of Orgovyx and why it is authorised in the EU

### What is Orgovyx and what is it used for?

Orgovyx is a medicine used to treat advanced cancer of the prostate (a gland of the male reproductive system) in adult patients when the cancer is 'hormone-sensitive', which means that it responds to treatments that reduce the levels of testosterone (the male sex hormone).

Orgovyx contains the active substance relugolix.

### How is Orgovyx used?

Orgovyx is available as tablets. The recommended dose is three tablets on the first day of treatment and then one tablet once a day taken around the same time each day.

The medicine can only be obtained with a prescription. For more information about using Orgovyx, see the package leaflet or contact your doctor or pharmacist.

### How does Orgovyx work?

The testicles produce testosterone which can make prostate cancer cells grow. The active substance in Orgovyx, relugolix, works by blocking a step in the process that signals the testicles to produce testosterone.

This step involves the release of a hormone called gonadotrophin-releasing hormone (GnRH) from the brain. By blocking the effects of GnRH, Orgovyx reduces the amount of testosterone in the body and slows down the growth of the prostate cancer cells.

### What benefits of Orgovyx have been shown in studies?

A main study involving 934 men with advanced hormone-sensitive prostate cancer showed that Orgovyx is effective at reducing the amount of testosterone to levels seen in men whose testicles have been surgically removed.

During the first year, 97% of the patients receiving Orgovyx had the required reduction of testosterone levels, compared with 89% of patients receiving leuprorelin (another medicine for prostate cancer). These results showed that Orgovyx was as effective as leuprorelin.

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## **What are the risks associated with Orgovyx?**

The most common side effects with Orgovyx (which may affect more than 1 in 5 people) are hot flushes, muscle and joint pain and tiredness. Other very common side effects are diarrhoea and constipation.

For the full list of side effects and restrictions for Orgovyx, see the package leaflet.

## **Why is Orgovyx authorised in the EU?**

The European Medicines Agency decided that Orgovyx's benefits are greater than its risks and it can be authorised for use in the EU.

A main study showed that Orgovyx was as effective as standard treatment with another medicine (leuprorelin) in reducing testosterone levels of patients with advanced hormone-sensitive prostate cancer. Orgovyx was generally well-tolerated by most of the patients. Its side effects were mild and manageable.

## **What measures are being taken to ensure the safe and effective use of Orgovyx?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Orgovyx have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Orgovyx are continuously monitored. Suspected side effects reported with Orgovyx are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Orgovyx**

Orgovyx received a marketing authorisation valid throughout the EU on 29 April 2022.

Further information on Orgovyx can be found on the Agency's website:

<https://www.ema.europa.eu/en/medicines/human/EPAR/orgovyx>

This overview was last updated in 04-2022.