

#### What is ORGOVYX?

ORGOVYX is a prescription medicine used in adults for the treatment of advanced prostate cancer.

It is not known if ORGOVYX is safe or effective in females or children.

#### **IMPORTANT SAFETY INFORMATION**

**Do not take ORGOVYX** if you have had a severe allergic reaction to relugolix or any of the ingredients in ORGOVYX.



# **ORGOVYX**

is **the only oral** androgen deprivation therapy (ADT) and was shown to **lower testosterone** and PSA levels\* in adults with advanced prostate cancer.

ORGOVYX is the only ADT medicine that **is not an injection**.



\*Even though it wasn't the main focus of the clinical trial, PSA (prostate-specific antigen) levels were monitored. Because the clinical trial included many different types of patients, the results of PSA monitoring should be interpreted with caution. No evidence has shown that the speed of PSA decline is related to a clinical benefit.

# IMPORTANT SAFETY INFORMATION (cont'd) What should I tell my healthcare provider before taking ORGOVYX?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any heart problems, including a condition called long QT syndrome.
- Are pregnant or plan to become pregnant. ORGOVYX can harm your unborn baby and cause loss of pregnancy (miscarriage).



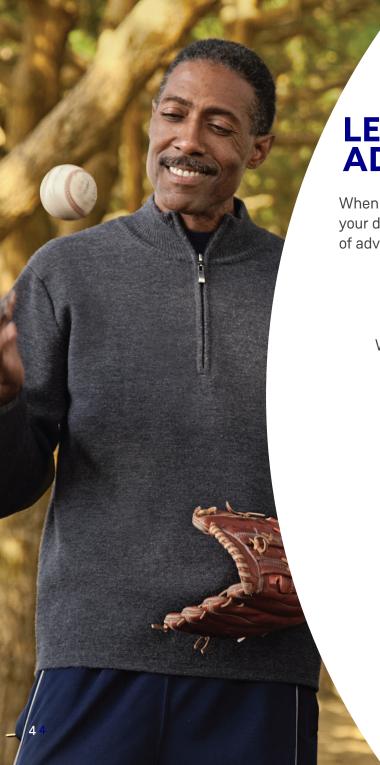
# YOUR GUIDE TO ORGOVYX

If you're living with advanced prostate cancer, it can feel overwhelming to consider what you should do next. Taking the time to learn all you can about your treatment is a good first step in finding a sense of control.

# IN THIS GUIDE

About advanced prostate cancer.	4
Testosterone's role in prostate cancer.	5
How ORGOVYX works.	8
How ORGOVYX may help	9
How to take ORGOVYX	13
Understanding side effects	15
Getting ORGOVYX	17
Patient support and financial assistance 1	19





# LEARNING ABOUT ADVANCED PROSTATE CANCER

When you were diagnosed with advanced prostate cancer, you may have heard your doctor say it was **recurrent**, **locally advanced**, or **metastatic**. These are types of advanced prostate cancer.

## Recurrent

When prostate cancer has returned—following initial treatment such as radiation therapy or surgery—as detected by a rising PSA\* level, biopsy, or scan

\*PSA stands for prostate-specific antigen.

## Locally Advanced

When prostate cancer has spread to tissues near the prostate

## **Metastatic**

When prostate cancer has spread far from the prostate to other parts of the body, such as the bones, liver, or lungs

# TESTOSTERONE'S ROLE IN PROSTATE CANCER

Testosterone is the male hormone that most prostate cancers need to grow. That's why advanced prostate cancer is often treated with hormone therapy, which helps lower the amount of testosterone the body makes. Your doctor may talk about a type of hormone therapy called ADT, or androgen deprivation therapy. Talk to your doctor about the benefits and risks of ADTs.

## There are 2 types of ADT medications—LHRH\* agonists and GnRH<sup>†</sup> antagonists

#### LHRH agonist examples



Lupron Depot® (leuprolide acetate for depot suspension)



Eligard® (leuprolide acetate for injectable suspension)

\*LHRH stands for luteinizing hormone-releasing hormone.

## **GnRH** antagonist examples



Firmagon® (degarelix for injection)



ORGOVYX® (relugolix)

<sup>†</sup>GnRH stands for gonadotropinreleasing hormone.

Lupron Depot is a registered trademark of AbbVie Inc. Eligard is a registered trademark of the Tolmar group. Firmagon is a registered trademark of Ferring B.V.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

What should I tell my healthcare provider before taking ORGOVYX? (cont'd)

Tell your healthcare provider about all of your medical conditions, including if you:

- Have a partner who is pregnant or may become pregnant.
- Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with ORGOVYX and for 2 weeks after the last dose of ORGOVYX.



# TESTOSTERONE'S ROLE IN PROSTATE CANCER

The 2 types of ADT medications work in different ways to lower testosterone

## LHRH agonists work by first activating some hormone receptors

When therapy is started, LHRH agonists turn on (or activate) certain hormone receptors. This increases testosterone levels before lowering them. This temporary rise in testosterone levels can last for a few weeks. It is called a "testosterone flare." The testosterone flare may worsen certain symptoms in some patients. If this happens, patients may need other treatments to help with the symptoms.



## **GnRH** antagonists work by directly blocking some hormone receptors

By directly blocking (or inhibiting) certain hormone receptors, GnRH antagonists lower testosterone levels without increasing them first. This results in lowering testosterone levels without causing a testosterone flare.



#### IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before taking ORGOVYX? (cont'd)

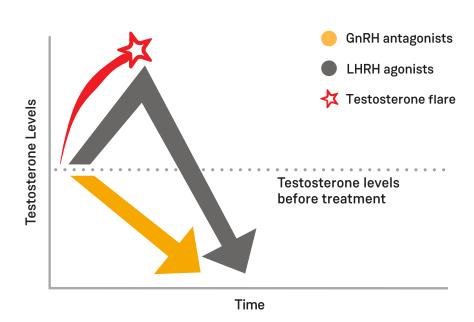
Tell your healthcare provider about all of your medical conditions, including if you:

• Are breastfeeding or plan to breastfeed. It is not known if ORGOVYX passes into your breast milk.



# TESTOSTERONE'S ROLE IN PROSTATE CANCER

## How GnRH antagonists and LHRH agonists affect testosterone



LHRH agonists can cause testosterone levels to first go up before they get lower. GnRH antagonists lower testosterone levels without causing a testosterone flare.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### What should I tell my healthcare provider before taking ORGOVYX? (cont'd)

**Tell your healthcare provider about all the medicines or treatments you receive,** including: prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking ORGOVYX with certain other medicines can affect how ORGOVYX works or may cause side effects.

You should not start or stop any medicine before you talk with your healthcare provider who prescribed ORGOVYX.



# **HOW ORGOVYX WORKS**

**Lowering testosterone is one of the main ways to treat advanced prostate cancer.** ORGOVYX works to lower the amount of testosterone your body makes. As a result, this helps lower the amount of testosterone in your body.

Imagine that the body makes testosterone the way that water comes out of a faucet



Without treatment, the faucet is turned on and testosterone flows freely.



With ORGOVYX, the faucet is almost turned off and the flow of testosterone is slowed. This means there is less testosterone.

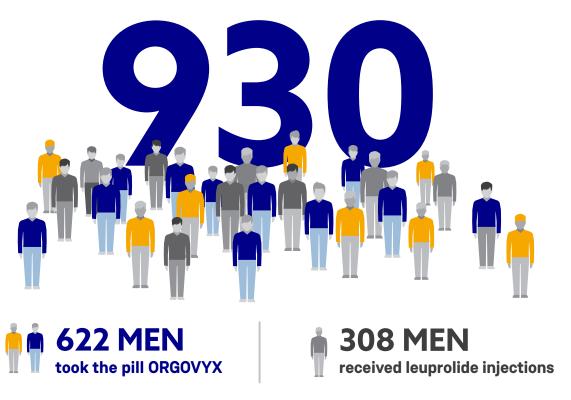


It's important to remember that lowering testosterone is one of the main ways to help manage advanced prostate cancer.

# IMPORTANT SAFETY INFORMATION (cont'd) What are the possible side effects of ORGOVYX?

- Serious side effects of ORGOVYX include changes in the electrical activity of your heart (QT prolongation). Your healthcare provider may check your body salts (electrolytes) and the electrical activity of your heart during treatment with ORGOVYX. Tell your healthcare provider right away if you get any signs or symptoms of QT prolongation, including dizziness, fainting, feeling that your heart is pounding or racing (palpitations), and chest pain.
- Serious side effects of ORGOVYX include allergic reactions. Stop taking ORGOVYX and tell your healthcare provider or get emergency medical help right away if you get any signs or symptoms of an allergic reaction, including swelling of your face, lips, tongue, throat, or trouble swallowing; trouble breathing; and hives (raised bumps), rash, or redness all over your body.

ORGOVYX was studied in a clinical trial with more than 900 men with advanced prostate cancer.



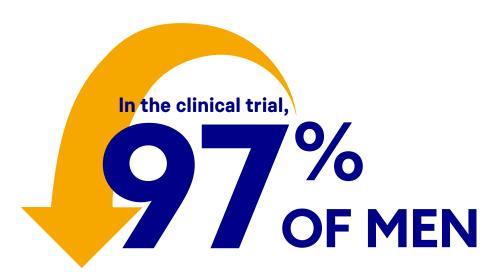
Men in the trial were treated for 48 weeks and either took the pill ORGOVYX or received leuprolide acetate injections. The purpose of the trial was to measure how well ORGOVYX **lowered testosterone** to the treatment goal of below 50 ng/dL from day 29 through week 48.

While it wasn't the main focus of the trial, the trial also monitored how much ORGOVYX was able to **lower PSA levels**.\*

\*Because the clinical trial included many different types of patients, the results of PSA monitoring should be interpreted with caution. No evidence has shown that the speed of PSA decline is related to a clinical benefit.



ORGOVYX was proven to lower testosterone and kept it low



taking ORGOVYX lowered their testosterone (below 50 ng/dL) by day 29 and kept it low through week 48.

For men receiving leuprolide injections, 89% lowered their testosterone by day 29 and kept it low through week 48.

It's important to know that everyone is unique and may see different results. Talk to your doctor about what these clinical trial results may mean for you.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

What are the possible side effects of ORGOVYX? (cont'd)

**Most common side effects of ORGOVYX include:** hot flushes, increased blood sugar levels, increased blood fat (triglyceride) levels, muscle and joint pain, decreased blood hemoglobin levels, increased liver enzymes, tiredness, constipation, and diarrhea.



## **ORGOVYX** was proven to lower testosterone levels fast

After 15 days of treatment, **99% of men taking ORGOVYX lowered their testosterone levels to below 50 ng/dL** in the clinical trial and 12% of men receiving leuprolide injections lowered their testosterone levels to below 50 ng/dL.





It's important to know that everyone is unique and may see different results. Talk to your doctor about what these clinical trial results may mean for you.

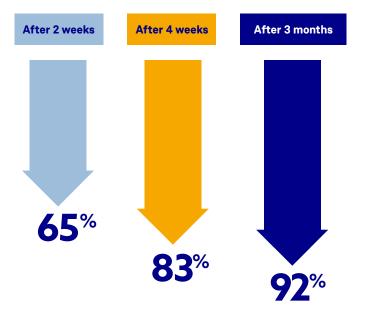
# IMPORTANT SAFETY INFORMATION (cont'd) What are the possible side effects of ORGOVYX? (cont'd)

ORGOVYX may cause other side effects including weight gain, decreased sex drive, and erectile function problems.



## ORGOVYX lowered PSA levels, on average, by 92% after 3 months

In the clinical trial, PSA levels were also monitored. During the first few months of taking ORGOVYX, men saw their PSA levels were lowered the longer they stayed on treatment, and kept them low throughout the 48-week trial.\*



**PSA** 

After 3 months, ORGOVYX continued to keep PSA levels low throughout the rest of the 48-week trial.

\*Even though it wasn't the main focus of the clinical trial, PSA (prostate-specific antigen) levels were monitored. Because the clinical trial included many different types of patients, the results of PSA monitoring should be interpreted with caution. No evidence has shown that the speed of PSA decline is related to a clinical benefit.

It's important to know that everyone is unique and may see different results. Talk to your doctor about what these clinical trial results may mean for you.

# IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ORGOVYX? (cont'd)

ORGOVYX may cause fertility problems in males, which may affect your ability to father children. Talk to your healthcare provider if this is a concern for you.



# **HOW TO TAKE ORGOVYX**

## ORGOVYX is a small once-daily pill that can fit into your routine

The recommended dose of ORGOVYX:

First day of treatment: Take 3 pills.



Pills not shown in actual size.

**Every day after that:** Take 1 pill once daily. Take it at about the same time each day.



## Things to remember while taking ORGOVYX



Take ORGOVYX exactly how your doctor prescribed



You can take ORGOVYX with or without food



**Swallow each pill whole**—do not crush or chew them



**Do not change your prescribed dose** of ORGOVYX or stop treatment without talking to your doctor first

Your doctor may change your dose of ORGOVYX as needed. If you have questions about your dose, check with your doctor.



# **HOW TO TAKE ORGOVYX**

What to do if you forget to take ORGOVYX



#### If it's been 12 hours or less

since you were supposed to take ORGOVYX, take it as soon as possible



#### If it's been more than 12 hours

since you were supposed to take ORGOVYX, don't take the missed dose.

Take your next ORGOVYX dose at your regular time the next day



**QUICK TIP:** A simple way to add ORGOVYX to your routine is to combine it with an activity you do every day already. For example, you can take your medicine with your morning coffee or at night, right before you get ready for bed.



# **UNDERSTANDING SIDE EFFECTS**

It's important to understand the benefits and risks when starting a treatment. Talk to your doctor about the possible side effects of ORGOVYX. They can help you understand what to do if you experience side effects.

### Before taking ORGOVYX, tell your doctor about all your medical conditions, including if you:

- Have any heart problems, including a condition called long QT syndrome
- Are pregnant or plan to become pregnant. ORGOVYX can harm your unborn baby and cause loss of pregnancy (miscarriage)
- Have a partner who is pregnant or may become pregnant
- Males who have female partners who are able to become pregnant should use effective birth control (contraception) during treatment with ORGOVYX and for 2 weeks after the last dose of ORGOVYX
- Are breastfeeding or plan to breastfeed. It is not known if ORGOVYX passes into your breast milk

## **ORGOVYX** may cause serious side effects

ORGOVYX may cause changes in the electrical activity of your heart. This is called QT prolongation. Your doctor may check your salt levels, also known as electrolytes, and the electrical activity of your heart while you are taking ORGOVYX.

Tell your doctor right away if you have any of these signs or symptoms:

- Dizziness
- Feeling that your heart is pounding or racing (palpitations)
- Fainting
- Chest pain

ORGOVYX may also cause allergic reactions. Stop taking ORGOVYX and tell your doctor or get emergency medical help right away if you get any signs or symptoms of an allergic reaction, including:

- Swelling of your face, lips, tongue, throat, or trouble swallowing
- Trouble breathing
- Hives (raised bumps), rash, or redness all over your body

**Tell your doctor about any side effects** that bother you or don't go away. Your doctor may be able to help you find ways to manage them.



# **UNDERSTANDING SIDE EFFECTS**

## Common side effects

The most common side effects men experienced while taking ORGOVYX were:



Hot flushes, also known as hot flashes



Decreased blood hemoglobin levels



Constipation



Increased blood sugar and/or increased blood fat (triglyceride) levels



Increased liver enzymes



Diarrhea



Muscle and joint pain



Tiredness

ORGOVYX may cause other side effects including weight gain, decreased sex drive, and erectile function problems.

ORGOVYX may cause fertility problems in males, which may affect your ability to father children. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of ORGOVYX. Call your doctor for medical advice about side effects or if you have a side effect that bothers you or does not go away.

You may report side effects of prescription drugs to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

In the clinical trial, 3.5% of men taking ORGOVYX stopped taking it due to side effects.



# **GETTING ORGOVYX**

## Once you're prescribed ORGOVYX, there are 2 ways to get it



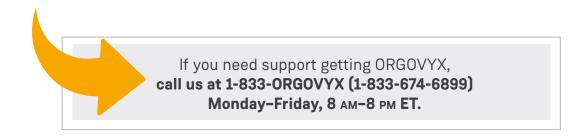
#### **Doctor's office**

Some doctors have their own in-office pharmacy. If yours does, you will likely get your ORGOVYX prescription there. Your doctor will work with you to help you get your medicine delivered right to your home.



## **Specialty pharmacy**

This type of pharmacy carries medicines that you can't get at regular pharmacies. A specialty pharmacy can deliver ORGOVYX right to your home.





To help you understand how to get ORGOVYX from a specialty pharmacy, just remember:





## 1. Paperwork

Your doctor's office will fill out the required paperwork. They will submit it to the specialty pharmacy.

**OUICK TIP:** Check with your doctor to make sure all of your forms are completed and ready to submit.



## 2. Pharmacy call

After your paperwork has been submitted, the specialty pharmacy will call you. They can help you understand how much your medicine may cost and will set up delivery. Answering this call is important. The specialty pharmacy will need to get in touch with you to finish processing your prescription.

**QUICK TIP:** Save the specialty pharmacy's number in your phone for easy reference. This will also help you recognize their number when they call you for refill reminders.



## 3. Prescription delivery

After your specialty pharmacy call, ORGOVYX will be delivered right to your home. If you need help during any step of this process, your doctor or specialty pharmacy can assist you.



# **SUPPORT TO GET YOU STARTED & HELP YOU STAY ON TRACK**



**The ORGOVYX Support Program** offers one-on-one support to help make your start on ORGOVYX as simple as possible and provides tools and resources to support you throughout treatment.



#### One-on-one nurse support

Once you are enrolled, our team of nurses\* is here to help answer general questions about ORGOVYX and offer lifestyle tips



#### Insurance coverage assistance

Information to help you understand your insurance benefits and coverage for ORGOVYX



#### Financial assistance

Help with financial support options, including copay assistance for eligible patients.

Terms and conditions apply<sup>†</sup>



#### **Educational resources**

Educational resources to help you get started on treatment, including a patient welcome kit



### Have questions about ORGOVYX?

We are here to support you. Our team is available Monday-Friday, 8 AM-8 PM ET. Call us at 1-833-ORGOVYX (1-833-674-6899).

- \*The ORGOVYX Support Program's nurse advice is not meant to replace your doctor's advice.
- $^{\scriptscriptstyle \dagger}$  See terms and conditions on page 20.



# **SUPPORT TO GET YOU STARTED & HELP YOU STAY ON TRACK**

ORGOVYX Support Coordinators are here to assist you in trying to find ways to get and pay for your medicine.

#### Help navigating insurance

Our Support Coordinators can help you understand your insurance benefits and coverage for ORGOVYX.

#### Payment support

We can help you learn about available financial assistance programs to help cover out-of-pocket costs for ORGOVYX.

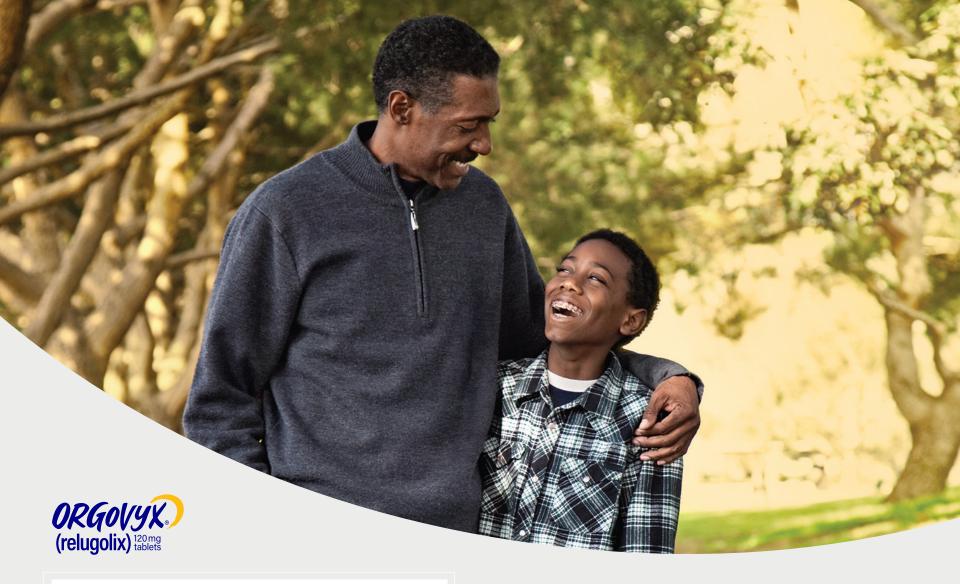
### Pay as little as \$10 per month for ORGOVYX\*

If you have insurance through your work or that you bought for yourself (often called commercial insurance), you may be eligible. Terms and conditions apply.\*

Learn more at orgovyx.com.

#### \*ORGOVYX Copay Assistance Program: Terms and Conditions

The ORGOVYX Copay Assistance Program ("Copay Program") is for eligible patients with commercial prescription insurance for ORGOVYX. With this Copay Program, eligible patients will pay as little as \$10 per month, subject to a maximum of \$10,000 per calendar year. After the annual maximum of \$10,000 for ORGOVYX is reached, patient will be responsible for the remaining monthly out-of-pocket costs. This Copay Program may not be redeemed more than once per 21 days. The Copay Program is not valid for patients whose prescription claims are reimbursed, in whole or in part, by any state or federal government program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program. Offer is not valid for cash-paying patients. Patient must be a resident of the U.S., Puerto Rico, or U.S. Territories. This Copay Program is void where prohibited by state law and on the date an AB generic equivalent for ORGOVYX becomes available. Certain rules and restrictions apply. This offer is not insurance. This offer cannot be combined with any other coupon, free trial, discount, prescription savings card, or other offer. This offer is not conditioned on any past, present, or future purchase, including refills. Patient and participating pharmacists agree not to seek reimbursement for all, or any part of the benefit received by the patient through this Copay Program. Patient and participating pharmacists agree to report the receipt of Copay Program benefits to any insurer or other third party who pays for or reimburses any part of the prescription filled using the Card, as may be required by such insurer or third party. Myovant Sciences reserves the right to revoke, rescind, or amend this offer without notice. The ORGOVYX Copay Program is valid through December 31, 2024.





If you have questions about ORGOVYX, we're here to help.

1-833-ORGOVYX (1-833-674-6899) Monday-Friday, 8 AM-8 PM ET



