ORGOVYX® SUPPORT PROGRAM

# Patient Start Form

## The ORGOVYX Support Program can provide your eligible patients with:

**Reimbursement support**
- Benefits investigation
- Prior authorization support

**Financial assistance***
- Copay Assistance Program
- Patient Assistance Program (PAP)

**Educational support**
- Helpful resources
- Nurse support

## Enrolling in the ORGOVYX Support Program is the first step to unlocking support. There are two ways to get started:

### ePrescribe via your EHR

Select Mercalis Pharmacy† and get started!

**Mercalis Pharmacy**
2250 Perimeter Park Drive
Morrisville, NC 27560-8892
NPI 1265453211

OR

### Fax this Start Form

If you are **not** ePrescribing, complete pages 1-5 of this form and fax the completed form to **1-844-826-8875**

## Once a prescription is received through the EHR or a faxed Patient Start Form...

- Benefits investigation and prior authorization support can get started
- ORGOVYX Support Program will reach out to patient to obtain consent
- **Prescriptions will be triaged to your preferred pharmacy**

**Remind patients they may receive a text or call from the ORGOVYX Support Program (1-833-674-6899).**
The ORGOVYX Support Program will contact patients to obtain consent, help enroll in support services, and confirm shipments for patients who qualify for free medication.

**Questions? Call 1-833-ORGOVYX (1-833-674-6899), Monday–Friday, 8 AM–8 PM ET.**

EHR=electronic health record.

*Financial assistance options available for eligible patients only.

†If unable to find Mercalis in the EHR platform, contact IT for support.

Hours of operation: Monday–Friday, 8 AM–8 PM ET
Phone: 1-833-ORGOVYX (1-833-674-6899) **FAX: 1-844-826-8875**
OrgovyxHCP.com | 2250 Perimeter Park Dr, Suite 300, Morrisville, NC 27560

Please see Important Safety Information on page 7 and full Prescribing Information and Patient Product Information for ORGOVYX (relugolix).

ORGOVYX® (relugolix) 120 mg tablets

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**FAX completed forms to 1-844-826-8875**

If you have questions or need more information, call 1-833-ORGOVYX (1-833-674-6899), Monday–Friday, 8 AM–8 PM ET, visit OrgovyxHCP.com, or write us at 2250 Perimeter Park Dr, Suite 300, Morrisville, NC 27560.

***Designates required fields.**

## Reimbursement support†

❑ Benefits Investigation ❑ Prior Authorization Assistance ❑ Appeal Assistance

**Will Prescriber communicate Reimbursement support results to Patient?**

☐ Yes, Prescriber has Patient's permission and will communicate results to Patient.

*(If no preference indicated, the ORGOVYX Support Program will provide results to both Prescriber and Patient).*

## Financial assistance†

**Evaluate Patient for:**

❑ Copay Assistance Program (for commercially insured patients)‡

❑ Patient Assistance Program (for uninsured or inadequately covered patients)‡

The ORGOVYX Support Program will complete a benefits investigation for the Patient Assistance Program unless your office submits a benefits investigation completed within the last 30 days.

†Full reimbursement support and copay assistance are provided, if no selection is made.
‡For full terms and conditions, please see page 6.

## Patient information

First Name* _____ Last Name* _____ Date of Birth* (MM/DD/YY) _____

Preferred Language ☐ English ☐ Spanish ☐ Other _____ Email _____

Address* _____ City* _____ State* _____ ZIP* _____

Home Phone* _____ Work Phone _____ Cell Phone* _____

Preferred Contact Phone Number ❑ Home ❑ Work ❑ Cell Best Time to Contact ❑ Morning ❑ Afternoon ❑ Evening
(You can select more than 1 option.)

OK to leave a message at your preferred contact phone number? ❑ Yes ❑ No

Alternate Contact: Name _____ Relationship to Patient _____ Phone _____

## Pharmacy benefit and medical insurance information

❑ Patient does not have insurance (if checked, skip this section).

**FOR THIS SECTION: Fill out the pharmacy and medical insurance information below OR fax copies of the patient's PHARMACY BENEFIT and MEDICAL insurance cards along with this form to 1-844-826-8875.**

Prescription Insurance Name* _____

Member Name _____ Group# _____ Prescription Insurance Phone _____

Member ID# _____ PCN# _____ BIN# _____

Medical Insurance Name* _____ Member Name _____

Medical Insurance Type ☐ Private/Commercial ☐ Medicare ☐ Medicaid Insurance Phone _____

Member ID# _____ Group# _____ Effective date _____

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***Designates required fields.**

## Patient authorization to share health information (to be completed by patient or patient representative)

### Authorization to Use and Disclose Protected Health Information (PHI):

By signing below, I authorize my HCPs and staff, health plan, and pharmacies, including Mercalis Intake Pharmacy (collectively, my "Healthcare Providers") to disclose individually identifiable information about me, my health or condition(s), treatment and care, insurance coverage, payment information, and medication history and prescriptions (collectively, "Protected Health Information") to Sumitomo Pharma America, Inc. and/or its designated affiliates, agents, representatives, and service providers (collectively, "Sumitomo Pharma America") for the following purposes:

- Seeing if I qualify, enrolling me in, and contacting me about the ORGOVYX Support Program and other ORGOVYX-related support programs (ie, Sumitomo Pharma America Patient Assistance Program)
- Providing me with ORGOVYX Support Program services, which may include the following (also referred to as "Patient Support Services"):
- Providing benefits investigation and reimbursement support, including help with prior authorization requirements or appealing a denied claim
- Sending my prescription to the in-network specialty pharmacy that dispenses ORGOVYX
- Providing me with financial assistance resources if I'm eligible, including copay assistance or free drug programs
- Communicating with my healthcare team about ORGOVYX and Patient Support Services
- Providing me with disease management and other educational materials
- Contacting me to ask me questions or sending me surveys about my experience with ORGOVYX and ORGOVYX-related programs to help Sumitomo Pharma America evaluate, improve, and develop products, services, materials, and programs related to my condition or treatment
- Communicating with me via telephone, email, the Internet, and/or text message (data rates may apply) to assist with adherence to my medication routine, and to provide community resources and referrals

### In addition, I understand and agree that:

- My Protected Health Information disclosed under this authorization may no longer be protected by state and federal law, including the Health Insurance Portability and Accountability Act (HIPAA), and may be subject to redisclosure by Sumitomo Pharma America
- This authorization is voluntary, but if I do not sign this authorization, I cannot take part in the Program
- I am not required to sign this authorization, and my Healthcare Providers will not otherwise condition my treatment, payment, health insurance enrollment, or eligibility for healthcare benefits to which I am otherwise entitled on whether I sign this authorization
- This authorization will last until I am no longer participating in the Program, sooner as limited by applicable state law or until it is revoked
- I may cancel my authorization at any time by mailing a written request to Sumitomo Pharma America Patient Assistance Program Administrators at 2400 Sand Lake Road, Suite 200, Orlando, FL 32809; however, cancellation of this authorization will end my enrollment in the Program. I further understand that canceling this Authorization will not affect any use or disclosure of my Protected Health Information that has already taken place in reliance on this authorization. I have a right to receive a copy of this authorization

**My signature below indicates that I have read, understand, and agree to the AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION (PHI):**

**Sign Here** **Patient Signature*:** _____ **Date*:** _____

If signed by legal representative of patient:

**Authorized Representative Signature†:** _____ **Date:** _____

**Printed Name of Authorized Representative†:** _____

**Authorized Representative Relationship to Patient:** _____

†A person with legal authority to make healthcare decisions on behalf of the individual.

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# PATIENT START FORM

**FAX completed forms to 1-844-826-8875**

If you have questions or need more information, call 1-833-ORGOVYX (1-833-674-6899), Monday–Friday, 8 AM–8 PM ET, visit OrgovyxHCP.com, or write us at 2250 Perimeter Park Dr, Suite 300, Morrisville, NC 27560.

***Designates required fields for enrollment in support services.**

## Patient authorization to obtain financial information and consent to program terms, conditions, and communications

**I understand the following statements:**

- The personal information that I provide to Sumitomo Pharma America is true and complete, and I agree that, at any time during my participation in the ORGOVYX Support Program, Sumitomo Pharma America may request additional documentation to verify my personal information
- I am not charged to enroll or participate in the ORGOVYX Support Program or required to purchase any Sumitomo Pharma America product
- The ORGOVYX Support Program may change or end at any time, without notice
- If I qualify for, and receive, copay assistance or free medication from Sumitomo Pharma America, I agree to comply with the program rules and agree that I will not seek or receive reimbursement for the assistance I receive from any third party, including from an insurance program, a health savings, flexible spending, or other health reimbursement account. If I have Medicare Part D, I will also not count any free medication I receive towards my true out-of-pocket costs (TrOOP)
- I understand that assistance may be temporary and I may be required to reapply as described in the program rules
- I will contact the ORGOVYX Support Program if my insurance changes or I am no longer prescribed ORGOVYX
- I understand that completing and signing the Patient Assistance Program (PAP) portion of this form does not guarantee my eligibility for the Sumitomo Pharma America Patient Assistance Program

### Other Consents Related to Participation in the ORGOVYX Support Program

**Credit Check Consent and PAP Terms and Conditions Consent**

*(Required for Sumitomo Pharma America Patient Assistance Program)*

❑ By checking this box and signing below, I confirm that I have read, understand, and accept the terms and conditions on page **6** for participating in the Sumitomo Pharma America Patient Assistance Program, and I grant permission to EvinceMed to provide the ORGOVYX Support Program with information from my credit/consumer profile for the sole purpose of determining if my income meets the eligibility standards of the Sumitomo Pharma America Patient Assistance Program.

**Copay Assistance Program Terms and Conditions Consent** *(Required for ORGOVYX Copay Assistance Program)*

❑ By checking this box and signing below, I confirm that I have read, understand, and accept the terms and conditions on page **6** for participating in the ORGOVYX Copay Assistance Program.

**Optional Promotional Communications**

❑ By checking this box and signing my name, I additionally grant my authorization for Sumitomo Pharma America to use my PHI to communicate with me about the benefits of Sumitomo Pharma America products and services, as described in the PATIENT AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION on page **2** of this form. I specifically consent to receive autodialed marketing texts from Sumitomo Pharma America and its service providers regarding Sumitomo Pharma America products and services at the cell phone number provided on page **1** of this form. I understand that providing this consent is not required or a condition of purchasing any products or services. I understand that I can opt out at any time.

**Sign Here** **Patient Signature*:** _____ **Date*:** _____

If signed by legal representative of patient:

**Authorized Representative Signature†:** _____ **Date:** _____

**Printed Name of Authorized Representative†:** _____

**Authorized Representative's Relationship to Patient:** _____

†A person with legal authority to make health care decisions on behalf of the individual.

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***Designates required fields.**

## Select preferred dispensing method*: Please select one only.

❑ In-Office/Clinic Dispensing Pharmacy or Hospital/Health System Dispensing Pharmacy _____

Pharmacy Contact Name _____ Office Phone _____

❑ Specialty Pharmacy (Please select specialty pharmacy below.)

❑ **Biologics** ❑ **Onco360**

## Prescriber information: Fill out your information and NPI number.

Practice Name* _____ Prescriber Name* _____

Specialty _____ NPI#* _____

Supervising/Collaborating Physician Name _____

Office Address* _____ City*_____ State* ____ ZIP* _____

Primary Office Contact Name _____ Office Phone* _____

Office Contact Email _____ Office Fax* _____

## Prescription: Fill out the prescription type that is relevant to your patient.

The prescriber is to comply with his/her state-specific prescription requirements, such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

Patient's DOB* (MM/DD/YY) _____ Patient's Full Name* _____

Anticipated ORGOVYX Start Date _____ Diagnosis/ICD-10-CM Code* _____

Patient's Current Medication List: _____

Patient's Known Drug Allergies: _____

### Healthcare Provider Certification and Consent

By signing on pages **2** and **3** of this form, I certify that I have obtained any and all consents from the patient or the patient's legal representative necessary under HIPAA and state law to permit the disclosure of protected health information, including that contained on this form and the HIPAA Authorization, to Sumitomo Pharma America and its contractors and agents for purposes relating to Sumitomo Pharma America, patient support programs, including assisting the patient with benefits investigation, prior authorization/appeals assistance, financial assistance resources and information, such as copay support or free drug programs, for which the patient may be eligible, and other support for ORGOVYX® (relugolix).

I certify that the patient (or the patient's legal representative) has provided consent to be contacted at the patient's phone number provided on this form by Sumitomo Pharma America and/or parties acting on its behalf, in relation to the patient's access to ORGOVYX.

For Pharmacy Triage: I give consent to Sumitomo Pharma America to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan. Transmission of this form shall be via fax or mail; verbal transmission does not constitute a valid prescription.

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# PATIENT START FORM

**FAX completed forms to 1-844-826-8875**

*Designates required fields.

**Prescription:** Fill out the prescription type that is relevant to your patient. (cont'd)

| Drug Name (NDC: 72974-120-01) | Directions<br>**Please review the section applicable to the regimen prescribed to the patient and check the box(es) that correspond(s) to the indicated regimen.**<br>(Please see dosage and administration section of the full Prescribing Information.) | Quantity | Refills |
|---|---|---|---|
| ORGOVYX® (relugolix) 120 mg tablets | **Preferred Dispensing Pharmacy Prescriptions**<br>**Please check the box(es) that correspond(s) to the prescribed dose regimen indicated for the patient.** | | Indicate number of refills below. |
| | ❑ **Loading dose followed by maintenance dose:** Take 3 tablets (360 mg) by mouth on the first day of treatment. After the first day, take 1 tablet (120 mg) by mouth once daily around the same time each day. | 30 tablets | NO REFILLS |
| | ❑ **Maintenance dose:** Take 1 tablet (120 mg) by mouth once daily around the same time each day. | 30 tablets | ____ |
| | ❑ **Loading dose followed by dose modification for use with combined P-gp and strong CYP3A inducers that cannot be avoided (per full Prescribing Information):** Take 3 tablets (360 mg) by mouth on the first day of treatment. After the first day, take 2 tablets (240 mg) by mouth once daily around the same time each day. | 60 tablets | NO REFILLS |
| | ❑ **Dose modification for use with combined P-gp and strong CYP3A inducers that cannot be avoided (per full Prescribing Information):** Take 2 tablets (240 mg) by mouth once daily around the same time each day. | 60 tablets | ____ |
| | **PAP Prescriptions ONLY**<br>**Please check the box(es) that correspond(s) to the prescribed dose regimen indicated for the patient. (PAP prescriptions will only be filled for advanced prostate cancer patients and must be consistent with the dosage recommendation in the full Prescribing Information.)** | | Indicate number of refills below. |
| | ❑ **Loading dose followed by maintenance dose:** Take 3 tablets (360 mg) by mouth on the first day of treatment. After the first day, take 1 tablet (120 mg) by mouth once daily around the same time each day. | 30 tablets | NO REFILLS |
| | ❑ **Maintenance dose:** Take 1 tablet (120 mg) by mouth once daily around the same time each day. | 90 tablets | ____ |
| | ❑ **Loading dose followed by dose modification for use with combined P-gp and strong CYP3A inducers that cannot be avoided (per full Prescribing Information):** Take 3 tablets (360 mg) by mouth on the first day of treatment. After the first day, take 2 tablets (240 mg) by mouth once daily around the same time each day. | 60 tablets | NO REFILLS |
| | ❑ **Dose modification for use with combined P-gp and strong CYP3A inducers that cannot be avoided (per full Prescribing Information):** Take 2 tablets (240 mg) by mouth once daily around the same time each day. | 180 tablets | ____ |

## Prescriber Declaration

By signing this form, I certify that this medication is medically necessary for the patient. I further certify that the information provided in this form is accurate to the best of my knowledge and that the patient meets the eligibility requirements of any ORGOVYX Support Program selected above, including without limitation, the requirement that the patient be prescribed ORGOVYX for an FDA-approved indication. I acknowledge and agree that I may not bill for medication dispensed under the Sumitomo Pharma America Patient Assistance Program to any private or government payer or other third party and that I will adhere to the terms and conditions of the ORGOVYX Support Program.

**Sign Here** **Prescriber's Signature*:** _____ ❑ Dispense as Written

(Wet signature is required.)

**Date*:** _____

## ORGOVYX COPAY ASSISTANCE PROGRAM TERMS, CONDITIONS, AND ELIGIBILITY CRITERIA

- To be eligible for the ORGOVYX Copay Assistance Program ("Copay Program"), patients must have commercial prescription insurance, have a valid prescription for an FDA-approved indication of ORGOVYX, be 18 years or older, and be a resident of the U.S., Puerto Rico, or U.S. Territories
- **The Copay Program is not valid for patients enrolled in 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 pharmaceutical assistance program. Patients may not use this offer if they are Medicare-eligible and enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees. Offer is not valid for cash-paying patients**
- The benefit under the Copay Program is offered to, and intended for the sole benefit of, eligible patients and may not be transferred to or utilized for the benefit of third parties, including, without limitation, third party payers, pharmacy benefit managers, or the agents of either
- Copay Card cannot be combined with any other external savings, free trial or similar offer for the specified prescription (including any program offered by a third party payer or pharmacy benefit manager, or an agent of either, that adjusts patient cost-sharing obligations, through arrangements that may be referred to as "accumulator" or "maximizer" programs)
- Third party payers, pharmacy benefit managers, or the agents of either, are prohibited from assisting patients with enrolling in the Copay Program
- With this Copay Program, eligible patients may pay as little as $10 per monthly prescription of ORGOVYX. This Copay Program is subject to a calendar year maximum savings of $10,000. After the calendar year maximum savings is reached, patient will be responsible for the remaining out-of-pocket costs for ORGOVYX
- This Copay Program may not be redeemed more than once per 21 days
- This card is valid for up to 12 prescription fills for a 30-day supply
- The Copay Program is good only in the U.S., Puerto Rico, or U.S. Territories at participating pharmacies. This Copay Program is void where prohibited by law and on the date an AB rated generic equivalent for ORGOVYX becomes available
- This offer is not health insurance
- This offer has no cash value and cannot be combined with any other coupon, free trial, discount, prescription savings card, or other similar offer for the specified prescription
- This offer is not conditioned on any past or future purchase, including refills
- This card is not transferable. The selling, purchasing, trading, or counterfeiting of this card is prohibited by law
- Patient and participating pharmacists agree not to seek reimbursement from any insurer or third party 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 Copay Program, as may be required by such insurer or third party
- Sumitomo Pharma America reserves the right to revoke, rescind, or amend this offer without notice
- **By redeeming this card, you acknowledge that you are an eligible patient and that you understand and agree to comply with the terms and conditions of this offer**

### PHARMACY INSTRUCTIONS:

**Pharmacist Instructions for a patient with an eligible third-party payer: When you redeem this card, you certify that you have not submitted and will not submit a claim for reimbursement under any federal, state, or other government health insurance programs for this prescription.**

- Process a Coordination of Benefits (COB/split bill) claim using the patient's prescription insurance for the PRIMARY claim. Submit a SECONDARY claim to PDMI using BIN: 610020 (No PCN required). **Offer not valid for discount cards, uninsured/cash patients.**
- Valid Other Coverage Code required. For any questions regarding processing, please call the Help Desk at 1-833-ORGOVYX (1-833-693-6899). Program managed by Mercalis on behalf of Sumitomo Pharma America, Inc.

## SUMITOMO PHARMA AMERICA PATIENT ASSISTANCE PROGRAM TERMS, CONDITIONS, AND ELIGIBILITY CRITERIA

The Sumitomo Pharma America Patient Assistance Program ("Program") provides ORGOVYX at no cost to eligible patients who are prescribed ORGOVYX for an FDA-approved indication. Patients and prescribers must complete the ORGOVYX Support Program enrollment form, and prescribers must provide a Patient Assistance Program prescription. To qualify, patients must meet Program eligibility requirements, which include, but are not limited to: (1) having no insurance or inadequate coverage for ORGOVYX; (2) meeting income guidelines and undergoing income evaluation; and (3) residing in the United States or US Territories. Patients may be required to apply to, and provide proof of denial from, various alternate funding sources in order to be eligible for Program enrollment. Program requires annual re-evaluation and re-enrollment for continued participation. Patient and participating prescribers agree not to seek reimbursement for all, or any part of, the free product received by the patient through this Program. Patients may not count the free product received from the ORGOVYX Support Program as an expense incurred for purposes of determining out-of-pocket costs for any plan, including true out-of-pocket costs ("TrOOP") for purposes of calculating the out-of-pocket threshold for Medicare Part D plans. Government health insured patients who meet the Program eligibility criteria are eligible to receive free product for the entire coverage year, and Sumitomo Pharma America will notify patients' government health insurance plans that the patient is enrolled in the Program. Patients who are not enrolled in government health insurance plans who qualify for Program assistance may be eligible for 12 months of free ORGOVYX at a time, as long as they continue to meet the Program eligibility requirements. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Other limitations may apply. Sumitomo Pharma America reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

## INDICATION

ORGOVYX® (relugolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

## IMPORTANT SAFETY INFORMATION

### Contraindication

ORGOVYX is contraindicated in patients with severe hypersensitivity to relugolix or to any of the product components.

### Warnings and Precautions

**QT/QTc Interval Prolongation:** Androgen deprivation therapy, such as ORGOVYX may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

**Hypersensitivity:** Angioedema was reported in 0.2% of patients treated with ORGOVYX in HERO. Hypersensitivity reactions, including pharyngeal edema and other serious cases of angioedema, have been reported in post-marketing with ORGOVYX. Advise patients who experience any symptoms of hypersensitivity to temporarily discontinue ORGOVYX and promptly seek medical care. Discontinue ORGOVYX for severe hypersensitivity reactions and manage as clinically indicated.

**Embryo-Fetal Toxicity:** The safety and efficacy of ORGOVYX have not been established in females. Based on findings in animals and mechanism of action, ORGOVYX can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of ORGOVYX.

**Laboratory Testing:** Therapy with ORGOVYX results in suppression of the pituitary gonadal system. Results of diagnostic tests of the pituitary gonadotropic and gonadal functions conducted during and after ORGOVYX may be affected. The therapeutic effect of ORGOVYX should be monitored by measuring serum concentrations of prostate-specific antigen (PSA) periodically. If PSA increases, serum concentrations of testosterone should be measured.

### Adverse Reactions

**Serious adverse reactions** occurred in 12% of patients receiving ORGOVYX. Serious adverse reactions in ≥0.5% of patients included myocardial infarction (0.8%), acute kidney injury (0.6%), arrhythmia (0.6%), hemorrhage (0.6%), and urinary tract infection (0.5%). Fatal adverse reactions occurred in 0.8% of patients receiving ORGOVYX including metastatic lung cancer (0.3%), myocardial infarction (0.3%), and acute kidney injury (0.2%). Fatal and non-fatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX.

**Most common adverse reactions (≥10%) and laboratory abnormalities (≥15%)** in patients receiving ORGOVYX were hot flush (54%), glucose increased (44%), triglycerides increased (35%), musculoskeletal pain (30%), hemoglobin decreased (28%), alanine aminotransferase increased (27%), fatigue (26%), aspartate aminotransferase increased (18%), constipation (12%), and diarrhea (12%).

### Drug Interactions

**Co-administration of ORGOVYX with a P-gp inhibitor** increases the area under the curve (AUC) and maximum concentration ($C_{max}$) of ORGOVYX, which may increase the risk of adverse reactions associated with ORGOVYX. Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions. Treatment with ORGOVYX may be interrupted for up to 2 weeks for a short course of treatment with certain P-gp inhibitors. If treatment with ORGOVYX is interrupted for more than 7 days, resume administration of ORGOVYX with a 360 mg loading dose on the first day, followed by 120 mg once daily.

**Co-administration of ORGOVYX with a combined P-gp and strong CYP3A inducer** decreases the AUC and $C_{max}$ of ORGOVYX, which may reduce the effects of ORGOVYX. Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg once daily.

**Please see Important Safety Information above and full Prescribing Information and Patient Product Information for ORGOVYX (relugolix).**



ORGOVYX® (relugolix) 120 mg tablets