ORGOVYX™
(relugolix) 120 mg tablets

# NOW APPROVED: ONE PILL, ONCE A DAY[1]

The only FDA-approved oral androgen deprivation therapy indicated for the treatment of **adult patients with advanced prostate cancer[1,2]**

**FIRST DAY OF TREATMENT**
- Take 3 pills
- 360 mg loading dose

**EVERY DAY AFTER THAT**
- Take 1 pill
- 120 mg daily dose

Pills not shown at actual size. Actual size: 10.7 mm x 7.5 mm x 5.2 mm.[3]

## After the initial loading dose, patients take one pill, once a day[1]

- Can be taken with or without food

- Should be taken around the same time each day

- For oral administration only—should be swallowed whole, not crushed or chewed

- Remind patients that it's important to take ORGOVYX as directed

- In patients treated with GnRH receptor agonists and antagonists for prostate cancer, treatment is usually continued upon development of nonmetastatic or metastatic castration-resistant prostate cancer
- No dosage adjustment required in patients with mild to severe renal impairment or mild or moderate hepatic impairment*
- Advise patients to take a missed dose of ORGOVYX as soon as they remember. If the dose was missed by more than 12 hours, patients should not take the missed dose and resume with the next scheduled dose
- Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first and separate dosing by at least 6 hours. Treatment with ORGOVYX may be interrupted for up to 2 weeks if a short course of treatment with a P-gp inhibitor is required
- If treatment with ORGOVYX is interrupted for more than 7 days, resume co-administration of ORGOVYX with a 360 mg loading dose on the first day, followed by 120 mg once a day
- 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 a day. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg

GnRH=gonadotropin-releasing hormone.

*The effect of end-stage renal disease with or without hemodialysis or severe hepatic impairment on the pharmacokinetics of ORGOVYX has not been evaluated.

Learn more about ORGOVYX by visiting orgovyxhcp.com

**Please see Important Safety Information on next page and full Prescribing Information for ORGOVYX.**

## INDICATION

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

## IMPORTANT SAFETY INFORMATION

### 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.

**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 full Prescribing Information for ORGOVYX.**

**References: 1.** ORGOVYX (relugolix) [prescribing information]. Brisbane, CA: Myovant Sciences, Inc.; 2020. **2.** Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. *N Engl J Med.* 2020;382(23):2187-2196. **3.** Data on file. Myovant Sciences, Inc.



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