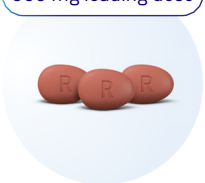
One pill, once a day, fits into the daily routine[1]

The only oral androgen deprivation therapy that offers **injection-free administration**[1]

FIRST DAY OF TREATMENT[1]

TAKE **3 pills**

360 mg loading dose



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

Pills not shown at actual size.

EVERY DAY AFTER THAT[1]

TAKE **1 pill**

120 mg daily dose

AFTER THE INITIAL LOADING DOSE, PATIENTS TAKE ONE PILL, ONCE A DAY[1]

Should be taken around the **same time each day**[1]

For oral administration only— tablets should be swallowed whole, not crushed or chewed[1]

Can be taken **with or without food**[1]

- 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[1]
- No dosage adjustment required in patients with mild to severe renal impairment or mild to moderate hepatic impairment[1]*
- 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[1]
- 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. Monitor patients for increased adverse reactions. Treatment with ORGOVYX may be interrupted for up to two weeks if a short course of treatment with a P-gp inhibitor is required. Resume ORGOVYX after the P-gp inhibitor is discontinued. If treatment with ORGOVYX is interrupted for greater than 7 days, restart ORGOVYX with a loading dose of 360 mg on the first day and continue with a dose of 120 mg once daily[1]
- 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[1]

*The effect of end-stage renal disease with or without hemodialysis or severe hepatic impairment on the pharmacokinetics of ORGOVYX has not been evaluated.[1]
CYP3A=cytochrome P450, family 3, subfamily A; GnRH=gonadotropin-releasing hormone; P-gp=P-glycoprotein.

INDICATION

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

LEARN MORE AT ORGOVYXHCP.COM

IMPORTANT SAFETY INFORMATION

Contraindication

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

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

ORGOVYX® (relugolix) 120 mg tablets

IMPORTANT SAFETY INFORMATION (continued)

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 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 an oral P-gp inhibitor increases relugolix exposure, 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 and separate dosing by at least 6 hours. Monitor patients for increased adverse reactions. Treatment with ORGOVYX may be interrupted for up to 2 weeks if a short course of treatment with a P-gp inhibitor is required. Resume ORGOVYX after the P-gp inhibitor is discontinued. If treatment with ORGOVYX is interrupted for greater than 7 days, restart ORGOVYX with a 360 mg loading dose on the first day and continue with 120 mg once daily.

Co-administration of ORGOVYX with a combined P-gp and strong CYP3A inducer decreases relugolix exposure, 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.

Reference: 1. ORGOVYX (relugolix). Prescribing information. Sumitomo Pharma America, Inc.; 2025.

Sumitomo Pharma

Pfizer Oncology

ORG-US-0443-25 02/26

ORGOVYX® (relugolix) 120 mg tablets