EU Prescribing Information

▼Orgovyx® (relugolix) 120 mg film-coated tablets

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Each tablet contains 120 mg of relugolix.

Indications: For the treatment of adult patients with advanced hormone-sensitive prostate cancer.

Dosage and Administration: Treatment with Orgovyx should be initiated and supervised by specialist physicians experienced in the medical treatment of prostate cancer. Treatment should be initiated with a loading dose of 360 mg (three tablets) on the first day, followed by a 120 mg (one tablet) dose taken once daily at approximately the same time each day. Because relugolix does not induce an increase in testosterone concentrations, it is not necessary to add an anti-androgen as surge protection at initiation of therapy. *Dose modification for use with P-gp inhibitors:* Co-administration of Orgovyx with oral P-glycoprotein (P-gp) inhibitors is not recommended. If co-administration is required, Orgovyx should be taken first and dosing should be separated 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. *Dose modification for use with combined P-gp and strong CYP3A inducers:* Co-administration of Orgovyx with combined P-gp and strong cytochrome P450 (CYP) 3A inducers is not recommended. If co-administration is required, the dose of Orgovyx must be increased to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, the recommended 120 mg dose of Orgovyx once daily must be resumed. *Missed doses:* If a dose is missed, Orgovyx must be taken as soon as the patient remembers. If the dose was missed by more than 12 hours, the missed dose must not be taken and regular dosing schedule should be resumed the following day. If treatment is interrupted for over 7 days, Orgovyx must be restarted with a loading dose of 360 mg on the first day, followed with a dose of 120 mg once daily. *Elderly:* No dose adjustment is required. *Renal impairment:* No dose adjustment in patients with mild, or moderate renal impairment is required. Caution is warranted in patients with severe renal impairment. *Hepatic impairment:* No dose adjustment in patients with mild or moderate hepatic impairment is required. *Paediatric population:* There is no relevant use of Orgovyx in children and adolescents under 18 years of age for the indication of treatment of advanced hormone sensitive prostate cancer. *Method of administration:* For oral use. Orgovyx can be taken with or without food. Tablets should be taken with some liquid as needed and swallowed whole.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Warnings and Precautions: *Effect on QT/QTc interval prolongation:* Androgen deprivation therapy may prolong the QT interval. In patients with a history of or risk factors for QT prolongation and in patients receiving concomitant medicinal products that might prolong the QT interval, physicians should assess the benefit risk ratio including the potential for Torsade de pointes prior to initiating Orgovyx. A thorough QT/QTc study showed that there was no intrinsic effect of relugolix on prolongation of the QTc interval. *Cardiovascular disease:* Cardiovascular disease such as myocardial infarction and stroke has been reported in patients with androgen deprivation therapy. Therefore, all cardiovascular risk factors should be taken into account. *Changes in bone density:* Long-term suppression of testosterone in men who have had orchiectomy or who have been treated with a GnRH receptor agonist or GnRH antagonist is associated with decreased bone density, which, in patients with additional risk factors, may lead to osteoporosis and increased risk of bone fracture. *Hepatic impairment:* Patients with known or suspected hepatic disorder have not been included in long-term clinical trials with relugolix. Mild, transient increases in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) have been observed but were not accompanied by an increase in bilirubin or associated with clinical symptoms. Monitoring of liver function in patients with known or suspected hepatic disorder is advised during treatment. The pharmacokinetics of relugolix in patients with severe hepatic impairment has not been evaluated. *Severe renal impairment:* Exposure to relugolix in patients with severe renal impairment may be increased by up to 2 fold. Because a lower dose of relugolix is not

available, caution in patients with severe renal impairment is warranted upon administration of a 120 mg dose of relugolix once daily. The amount of relugolix removed by haemodialysis is unknown. *Prostate-specific antigen (PSA) monitoring:* The effect of Orgovyx should be monitored by clinical parameters and prostate-specific antigen (PSA) serum levels. *Excipients*: This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'. *Effects on ability to drive and use machines:* Fatigue and dizziness are adverse reactions that may influence the ability to drive and use machines.

Fertility, Pregnancy & Lactation: This medicinal product is not indicated in women of childbearing potential. It is not to be used in women who are, or may be, pregnant or breast-feeding. It is not known whether relugolix or its metabolites are present in semen. *Contraception*: If a patient engages in sexual intercourse with a woman of childbearing potential, effective contraception during treatment and for 2 weeks after the last dose of Orgovyx must be used. *Pregnancy*: There is a limited amount of data from the use of relugolix in pregnant women. Based on the pharmacological effects, an adverse effect on pregnancy cannot be excluded. *Breast-feeding*: No data are available regarding the presence of relugolix or its metabolites in human milk or its effect on the breast-fed infant. An effect on breast-feeding newborns/infants cannot be excluded. *Fertility*: Orgovyx may impair fertility in males of reproductive potential.

Adverse Events include:
Adverse events which could be considered serious: Myocardial infarction, QT prolonged, angioedema.

Other Very Common adverse events: Hot flush, diarrhoea, constipation, musculoskeletal pain, fatigue.

Other Common adverse events: Anaemia, gynaecomastia, insomnia, depression, dizziness, headache, hypertension, nausea, hyperhidrosis, rash, libido decreased, weight increased, glucose increased, triglyceride increased, blood cholesterol increased.

See SmPC for details of other adverse events.

Legal Category: POM

Further information is available from: Accord-UK Ltd, Whiddon Valley, Barnstaple, Devon, EX32 8NS.

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Adverse events should be reported. Reporting forms and information can be found at https://www.adrreports.eu/ or directly via the national reporting system listed in Appendix V of the EU Smpc.

Adverse events should also be reported to Accord Healthcare Ltd via email medinfo@accord-healthcare.com or on +44(0)1271385257