Relugolix Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Treatment of adult patients with advanced hormone-sensitive prostate cancer (HSPC).	C61	00830a	CDS 01/01/2024

*This is for post 2012 indications only

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Relugolix is administered orally, once daily starting with a loading dose of 360 mg orally on day 1, followed by 120 mg once daily thereafter until disease progression or unacceptable toxicity develops.

Day	Drug	Dose	Route	Cycle
1	Relugolix	360mg	PO	Cycle 1, Day 1 only (loading dose)
2 and onwards	Relugolix	120mg	PO	Cycle 1, Day 2 and onwards
Relugolix can be taken with or without food. Tablets should be taken with some liquid as needed and should be swallowed whole.				
Tablets should be taken at approximately the same time each day.				
If a dose is missed, relugolix 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 with relugolix is interrupted for greater than 7 days, relugolix must be restarted with a loading dose of 360mg on the first day, followed with a dose of 120 mg once daily.				

ELIGIBILITY:

- Indications as above
- Histologically or cytologically confirmed adenocarcinoma of the prostate
- ECOG status 0-2

EXCLUSIONS:

- Hypersensitivity to relugolix or any of the excipients

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant with expertise in the treatment of prostate carcinoma.

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Blood glucose
- Bone profile
- ECG

Regular tests:

- FBC, renal and liver profile
- Blood glucose
- Bone profile as clinically indicated
- ECG as clinically indicated

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.
- If treatment with relugolix is interrupted for greater than 7 days, relugolix must be restarted with a loading dose of 360mg on the first day, followed with a dose of 120 mg once daily thereafter.
- The co-administration of relugolix with oral P-glycoprotein (P-gp) inhibitors and combined P-gp and strong CYP3A inducers must be avoided. If co-administration is unavoidable, the following dose modifications are recommended.

Dose modification for use with P-gp inhibitors:

- Relugolix administered first and dosing of the P-gp inhibitor should be separated by at least 6 hours.
- Treatment with relugolix 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:

- The dose of relugolix 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 relugolix once daily must be resumed.

Renal and Hepatic Impairment:

Table 1: Dose modification of relugolix in renal and hepatic impairment

Renal Impairment	Hepatic Impairment
No dose adjustment in patients with mild or moderate renal impairment is required. Caution is warranted in patients with severe renal impairment.	No dose adjustment in patients with mild or moderate hepatic impairment is required.
Renal and hepatic dose modifications from SmPC	

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting - Available on the NCCP website

Relugolix**:** Minimal **(Refer to local policy).**

For information:

Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists. Information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for Inclusion in NCIS (Medical Oncology) - Available on the NCCP website
- NCCP Supportive Care Antiemetic Medicines for Inclusion in NCIS (Haemato-oncology) - Available on the NCCP website

PREMEDICATIONS: Not usually required

OTHER SUPPORTIVE CARE: Not usually required

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics for details.

This medicinal product is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

REFERENCES:

1. Shore ND et al; HERO Study Investigators. Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer. N Engl J Med. 2020 Jun 4;382(23):2187-2196. doi: 10.1056/NEJMoa2004325. Epub 2020 May 29. PMID: 32469183.
2. Relugolix (Orgovyx®) SmPC. Last updated: 24/07/2024. Accessed October 2024.Available at: https://www.ema.europa.eu/en/documents/product-information/orgovyx-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1	02/01/2024		Prof Maccon Keane
2	03/04/2024	Updated prescriptive authority.	Prof Maccon Keane
3	09/12/2024	Regimen reviewed. Updated eligibility section. Updated baseline and regular testing sections. Updated regimen in line with NCCP standardisation.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.