

Leuporelin 11.25mg Therapy- 12 weeks

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Management of prostatic carcinoma for which a suppression of testosterone is indicated	C61	00492a	CDS

TREATMENT:

Leuporelin 11.25mg is administered as a single subcutaneous or intramuscular injection once every **12 weeks** until disease progression or unacceptable toxicity develops.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	Leuporelin	11.25mg	SC or IM	n/a	Every 12 weeks

ELIGIBILITY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to leuporelin or any of the excipients
- As sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases

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
- Bone profile
- Blood glucose

Regular tests:

- FBC, renal and liver profile as clinically indicated
- Blood glucose and bone profile 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.

NCCP Regimen: Leuporelin 11.25mg Therapy-12 weeks	Published: 30/05/2018 Review: 10/06/2025	Version number: 2
Tumour Group: Genitourinary NCCP Regimen Code: 00492	ISMO Contributor: Prof Maccon Keane	Page 1 of 3
<p>The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician, and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer</p> <p><i>This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens</i></p>		

DOSE MODIFICATIONS:

- No recommended dose modifications.

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

Renal Impairment	Hepatic Impairment
No dose modification necessary	No dose modification necessary

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal (Refer to local policy).

PREMEDICATIONS: None

OTHER SUPPORTIVE CARE:

Calcium and vitamin D supplementation (Refer to local policy).

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- Transient testosterone flare:** Leuprorelin acetate, like other gonadotropin releasing hormone (GnRH) agonists, causes a transient increase in serum concentrations of testosterone, dihydrotestosterone and acid phosphatase during the first week of treatment. Patients may experience worsening of symptoms or onset of new symptoms, including bone pain, neuropathy, haematuria, or ureteral or bladder outlet obstruction. These symptoms usually subside on continuation of therapy. Additional administration of an appropriate antiandrogen should be considered beginning 3 days prior to leuprorelin therapy and continuing for the first two to three weeks of treatment. This has been reported to prevent the sequelae of an initial rise in serum testosterone.
- If spinal cord compression or renal impairment due to ureteric obstruction are present or develop, specific standard treatment of these complications should be instituted.
- Bone Mineral Density:** The use of GnRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an GnRH agonist may reduce bone mineral loss. Particular caution is necessary in patients with additional risk factors for osteoporosis (e.g. chronic alcohol abusers, smokers, long-term therapy with anticonvulsants or corticosteroids, family history of osteoporosis).
- Glucose Tolerance:** Hyperglycemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Hyperglycemia may represent development of diabetes mellitus or worsening of glycemic control in patients with diabetes. Monitor blood glucose and/or glycosylated hemoglobin (HbA1c) periodically in patients receiving a GnRH agonist and manage with current practice for treatment of hyperglycemia or diabetes.

NCCP Regimen: Leuprorelin 11.25mg Therapy-12 weeks	Published: 30/05/2018 Review: 10/06/2025	Version number: 2
Tumour Group: Genitourinary NCCP Regimen Code: 00492	ISMO Contributor: Prof Maccon Keane	Page 2 of 3
<p>The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician, and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer</p> <p><i>This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens</i></p>		

DRUG INTERACTIONS:

- Since androgen deprivation treatment may prolong the QT interval, the concomitant use of leuprorelin with medicinal products known to prolong the QT interval or medicinal products able to induce Torsade de pointes should be carefully evaluated
- Current drug interaction databases should be consulted for more information.

ATC CODE:

Leuprorelin L02AE02

REFERENCES:

1. Loblaw DA, Virgo KS, Nam R, et al. Initial hormonal management of androgen-sensitive metastatic, recurrent, or progressive prostate cancer: update of an American Society of Clinical Oncology practice guideline. J Clin Oncol 2006;25(12):1596-1605
2. PROSTAP 3 DCS 11.25 mg[®] Summary of Product Characteristics Accessed May 2020. Available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2229-009-001_28052020110930.pdf

Version	Date	Amendment	Approved By
1	30/05/2018		Prof Maccon Keane
2	10/06/2020	Regimen review	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

NCCP Regimen: Leuprorelin 11.25mg Therapy-12 weeks	Published: 30/05/2018 Review: 10/06/2025	Version number: 2
Tumour Group: Genitourinary NCCP Regimen Code: 00492	ISMO Contributor: Prof Maccon Keane	Page 3 of 3
<p>The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician, and is subject to HSE's terms of use available at http://www.hse.ie/eng/Disclaimer</p> <p><i>This information is valid only on the day of printing, for any updates please check www.hse.ie/NCCPchemoregimens</i></p>		