

Leuprorelin 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

**If the reimbursement status is not defined¹, the indication has yet to be assessed through the formal HSE reimbursement process.*

TREATMENT:

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

The injected solution provides continuous release of leuprorelin acetate over a three-month period.

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

ELIGIBILITY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to leuprorelin 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.

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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 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 LHRH agonists may cause reduction in bone mineral density. In men, preliminary data suggest that the use of a bisphosphonate in combination with an LHRH 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. A reduction in glucose tolerance has been observed in males receiving LHRH agonists. This may manifest as diabetes or loss of glycaemic control in those with pre-existing diabetes mellitus. Consideration should therefore be given to monitoring of blood glucose levels in patients receiving a LHRH agonist.

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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 L02AE03

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 April 2018 Available at https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1547-003-004_27102016162059.pdf

Version	Date	Amendment	Approved By
1	30/05/2018		Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

ⁱ ODMS – Oncology Drug Management System

CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes

Further details on the Cancer Drug Management Programme is available at;

<http://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/cdmp/>

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