

Leuprorelin 22.5mg Therapy- 12 weeks

INDICATIONS FOR USE:

| INDICATION | ICD10 | Regimen Code | *Reimbursement Status |
|--|-------|--------------|-----------------------|
| Treatment of hormone dependent advanced prostate cancer | C61 | 00479a | CDS |
| Treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy | C61 | 00479a | CDS |

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

TREATMENT:

Leuprorelin 22.5mg is injected subcutaneously 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 | 22.5mg | SC | 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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| NCCP Regimen: Leuprorelin 22.5mg Therapy-12 weeks | Published: 30/05/2018 Review: 30/05/2020 | Version number: 1 |
| Tumour Group: Genitourinary NCCP Regimen Code: 00479 | ISMO Contributor: Prof Maccon Keane | Page 1 of 3 |
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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:** Hyperglycaemia and an increased risk of developing diabetes have been reported in men receiving GnRH agonists. Hyperglycaemia may represent development of diabetes mellitus or worsening of glycaemic 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 hyperglycaemia or diabetes. A reduction in glucose tolerance has been observed in males receiving LHRHagonists. 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. ELIGARD 22.5mg[®] Summary of Product Characteristics Accessed April 2018 Available at https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA1241-003-002_08122017095055.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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