

Goserelin 10.8mg Therapy- 12 weeks

INDICATIONS FOR USE:

| INDICATION | ICD10 | Regimen Code | *Reimbursement Status |
|---|-------|--------------|-----------------------|
| Treatment of locally advanced or metastatic hormone sensitive prostate cancer | C61 | 00477a | CDS |

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

TREATMENT:

Goserelin 10.8mg is injected subcutaneously into the anterior abdominal wall once every 12 weeks until disease progression or unacceptable toxicity develops.

| Day | Drug | Dose | Route | Diluent & Rate | Cycle |
|-----|-----------|--------|-------|----------------|----------------|
| 1 | Goserelin | 10.8mg | SC | n/a | Every 12 weeks |

Use extra care when administering goserelin to patients with a low BMI and/or who are receiving full anticoagulation medication

ELIGIBILITY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to goserelin 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 as clinically indicated
- Bone profile
- Blood glucose

Regular tests:

- FBC, renal and liver profile
- 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: Goserelin Therapy-12 weeks | Published: 30/05/2018 Review: 30/05/2020 | Version number: 1 |
| Tumour Group: Genitourinary NCCP Regimen Code: 00477 | 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 goserelin 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.

- Tumour Flare:** Luteinizing hormone-releasing hormone (LHRH) agonists (e.g. goserelin, leuprorelin and triptorelin) can cause short-term (2 to 3 weeks) stimulation of testosterone before suppression of androgen production, which may cause new or worsening signs and symptoms e.g. increased bone pain. This syndrome can be prevented by administering an antiandrogen 1 to 2 weeks before first dose of gonadotrophin releasing hormone agonists and continuing for approximately 1 month in total.
- The use of goserelin in men at particular risk of developing ureteric obstruction or spinal cord compression should be considered carefully and the patients monitored closely during the first month of therapy. 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:** 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.

DRUG INTERACTIONS:

- Since androgen deprivation treatment may prolong the QT interval, the concomitant use of goserelin 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:

Goserelin L02AE03

| | | |
|---|---|-------------------|
| NCCP Regimen: Goserelin Therapy-12 weeks | Published: 30/05/2018 Review: 30/05/2020 | Version number: 1 |
| Tumour Group: Genitourinary NCCP Regimen Code: 00477 | 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> | | |

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. Zoladex[®] Summary of Product Characteristics Accessed April 2018 Available at <http://www.medicines.ie/medicine/4780/SPC/Zoladex+LA+10.8mg/>

| 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/>

| | | |
|---|---|-------------------|
| NCCP Regimen: Goserelin Therapy-12 weeks | Published: 30/05/2018 Review: 30/05/2020 | Version number: 1 |
| Tumour Group: Genitourinary NCCP Regimen Code: 00477 | 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> | | |