Regimen Monograph

A - Regimen Name

GOSE Regimen

Goserelin

Disease Site	Genitourinary - Prostate
Intent	Neoadjuvant Adjuvant Palliative
Regimen Category	**Evidence-Informed :** Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.
Rationale and Uses	• for cytoreduction before brachytherapy • in combination with radiotherapy for the treatment of high-risk localized prostate cancer • for palliative treatment of recurrent, progressive or metastatic prostate cancer
Supplementary Public Funding	**goserelin** ODB - General Benefit

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B - Drug Regimen

goserelin

3.6 mg	SC depot	EVERY 4 WEEKS
OR		
10.8mg	SC depot	EVERY 3 MONTHS (Q 13 weeks)

(Outpatient prescription in fixed-dose injection kits of 3.6mg and 10.8mg depot)

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C - Cycle Frequency

Goserelin: Every 4 or 13 weeks depending on formulation

- Neoadjuvant - Generally up to 6 months in duration
- Adjuvant - Generally up to 3 years
- Palliative - for non-metastatic disease (for example: rising PSA after radiation), use an intermittent schedule. Otherwise use continuously.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Not applicable

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and could be considered.

See appendix 6 for general recommendations.

Dosage with toxicity

Dosage with myelosuppression: No adjustment required.

Hepatic Impairment

No adjustment required.

Renal Impairment

No adjustment required.

Dosage in the elderly:

No adjustment required.

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F - Adverse Effects

Refer to goserelin drug monograph(s) for additional details of adverse effects

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life Threatening
• Hypogonadism and symptoms of ↓ testostorone • Disease flare – may be severe (may use short-term antiandrogen therapy for blockade of testosterone flare) • Diarrhea / constipation • Urinary symptoms • Insomnia • Hypertension	• Cardiotoxicity • Arrhythmia • QT prolongation • Arterial/venous thromboembolism • Osteopenia / osteoporosis • Pituitary hemorrhage • Hypersensitivity • Injection site injury/vascular injury • Increased LFTs • Glaucoma • Renal failure

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G - Interactions

Refer to goserelin drug monograph(s) for additional details

- Caution with concomitant QT-prolonging drugs, as androgen deprivation can have an additive QT-prolonging effect.

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H - Drug Administration and Special Precautions

Refer to goserelin drug monograph(s) for additional details

Administration:

- Subcutaneous injection of the depot into the anterior abdominal wall, below the naval line. Injection usually given at the Cancer Centre or physician's office. Should be administered by a healthcare professional experienced in administering deep subcutaneous injections under the supervision of a physician. Drug supplied by outpatient prescription.
- Store in original packaging between 2ºC and 25ºC. Protect from light and moisture.

Contraindications:

- Patients who have a hypersensitivity to this drug or any of its components.
- Females with undiagnosed abdominal vaginal bleeding.

Other Warnings/Precautions:

- Use with caution in patients with osteoporosis (or risk factors for osteoporosis), diabetes, risk factors for QT prolongation, history of depression, cardiovascular disease, metastatic vertebral lesions and/or urinary tract obstruction due to the risk of disease flare.
- Patients who experience anaphylaxis/anaphylactoid shock while on goserelin may require removal of the implant. If implant removal is necessary, it may be located by ultrasound.
- Goserelin requires administration by deep subcutaneous injection and is not recommended in patients with low body mass index (BMI <18.5) or in patients who are fully anticoagulated (INR >2).

Other Drug Properties:

- Carcinogenicity: No

Pregnancy and Lactation:

- Genotoxicity: No
- Embryotoxicity: Yes
- Fetotoxicity: Yes
  Not recommended for use in pregnancy. Adequate non-hormonal contraception must be used by most sexes during treatment and for at least 6 months after goserelin cessation (general recommendation).
- Breastfeeding: Not recommended
  Goserelin is secreted into milk in animals.
- Fertility effects: Fertility may be affected in males and females, but may be reversible.

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- Blood glucose; especially in diabetic patients or patients at risk of hyperglycemia; basaeline and periodic
- Electrolytes, including calcium and magnesium; baseline, also regularly in patients at risk
- Clinical assessment of disease flare, osteoporosis, symptoms of hypogonadism, injection site reactions, cardiovascular effects, signs of abdominal hemorrhage; at each visit

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Monitor bone and prostatic lesions; periodic

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J - Administrative Information

Outpatient prescription; drug administration at Cancer Centre or physician's office

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K - References

Bolla M, Gonzalez D, Warde P, et al. Improved survival in patients with locally advanced prostate cancer treated with radiotherapy and goserelin. N Engl J Med 1997;337(5):295-300.

Crook JM, O'Callaghan CJ, Duncan G, et al. Intermittent androgen suppression for rising PSA levels after radiotherapy. N Engl J Med 2012;367:895-903.

Denham JW, Steigler A, Lamb DS, et al. Short-term neoadjuvant androgen deprivation and radiotherapy for locally advanced prostate cancer: 10-year data from the TROG 96.01 randomised trial. Lancet Oncol 2011;12(5):451-9.

Goserelin drug monograph, Cancer Care Ontario.

Heidenreich A, Bellmunt J, Bolla M, et al. EAU Guidelines on Prostate Cancer. Part 1: Screening, Diagnosis, and Treatment of Clinically Localised Disease. European Urology 2011;59:61-71.

Kaisary AV, Tyrrell CJ, Peeling WB, et al. Comparison of LHRH analogue (Zoladex) with orchiectomy in patients with metastatic prostatic carcinoma. Br J Urol 1991;67(5):502-8.

Mottet N, Bellmunt J, Bolla M, et al. EAU guidelines on prostate cancer. Part II: Treatment of advanced, relapsing, and castration resistant prostate cancer. European Urology 2011:59;572-83.

Sarosdy MF, Schellhammer PF, Soloway MS, et al. Endocrine effects, efficacy and tolerablity of a 10.8-mg depot formulation of goserelin acetate administered every 13 weeks to patients with advanced prostate cancer. Br J Urol Int 1999;83(7):801-6.

Turkes AO, Peeling WB, Griffiths K. Treatment of patients with advanced cancer of the prostate: phase III trial, Zoladex against castration; a study of the British Prostate Group. J Steroid Biochem 1987;27(1-3):543-9.

March 2016 replaced regimen category, updated adverse effects, added interactions, administration, precautions

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M - Disclaimer

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