Regimen Monograph

A - Regimen Name

GOSE Regimen

Goserelin

Disease Site

Breast

Intent

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

- Palliative treatment of advanced breast cancer in pre- and perimenopausal women whose tumours contain estrogen and/or progesterone receptors
- Adjuvant therapy of early breast cancer in pre- and perimenopausal women whose tumours contain estrogen and/or progesterone receptors who are unsuitable for, intolerant to, or decline chemotherapy

Supplementary Public Funding

goserelin
ODB - General Benefit (goserelin)

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B - Drug Regimen

goserelin	3.6 mg	SC	Day 1

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

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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.

Dosage with toxicity

Dosage with myelosuppression: No adjustment required.

Hepatic Impairment

No adjustment required.

Renal Impairment

No adjustment required. (Although half-life is longer in patients with CrCl < 20 mL/min, it is not likely to cause drug accumulation.)

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

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Hot flashes, other estrogen deprivation symptoms	n/a	• Nausea/vomiting • Diarrhea	• Tumour flare • Mood (or personality) changes • Hypertension • Cardiotoxicity • Arrhythmia, QT interval prolonged • Arterial / Venous thromboembolism • Hypersensitivity • Injection site / vasular injury • Pituitary hemorrhage • Glucose intolerance • Glaucoma • Osteoporosis • Renal failure

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G - Interactions

Refer to goserelin drug monograph(s) for additional details

- Exercise caution when given with drugs that may prolong the QT interval
- Suppression of pituitary-gonadal system by GnRH may interfere with diagnostic tests of

pituitary-gonadal function.

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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 navel line.
- Injection usually given at the Cancer Centre or physician's office. Drug supplied by outpatient prescription.
- Should be administered by a healthcare professional experienced in administering deep subcutaneous injections under the supervision of a physician.
- Store in original packaging between 2°C and 25°C. Protect from light and moisture.

Contraindications and Precautions:

- Contraindicated in patients who have a hypersensitivity to this drug or any of its components, and in females with undiagnosed abnormal vaginal bleeding
- Use with caution in patients with osteoporosis (or risk factors for osteoporosis), diabetes, risk factors for QT prolongation, history of depression, cardiovascular disease, or at 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 recomended in patients with low body mass (BMI <18.5) or in patients who are fully anticoagulated (INR >2).

Pregnancy & lactation:

- Not recommended for use in pregnancy. Adequate non-hormonal contraception must be used by both sexes during treatment and for at least 6 months after goserelin cessation
- Breast feeding is not recommended.

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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/HbA1c levels; baseline and periodical, especially in diabetic patients
- EKG, Electrolytes, (including K, Ca, Mg); baseline and periodic for at risk patients
- Clinical assessment of disease flare, local reactions, thromboembolism, cardiovascular effects, osteoporosis, psychiatric effects, hot flashes, 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 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

Goserelin drug monograph, Cancer Care Ontario.

Hackshaw A, Baum M, Fornander T, Nordenskjold B, Nicolucci A et al. Long-term effectiveness of adjuvant goserelin in premenopausal women with early breast cancer. J Natl Cancer Inst. 2009 Mar 4;101(5):341-9.

Jonat W, Kaufmann M, Sauerbrei W, Blamey, R, Cuzick J. Goserelin Versus Cyclophosphamide, Methotrexate, and Fluorouracil as Adjuvant Therapy in Premenopausal Patients With Node-Positive Breast Cancer: The Zoladex Early Breast Cancer Research Association Study. J Clin Oncol. 2002 Dec 15; 20(24):4628-35.

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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