Regimen Monograph

A - Regimen Name

DGRL Regimen

Degarelix

Disease Site
Genitourinary
Prostate

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
For patients with advanced prostate cancer in whom androgen deprivation is warranted*.
*Marketing approval was based on testosterone suppression to castrate levels over a 1 year treatment period.

Supplementary Public Funding
degarelix
ODB - General Benefit (degarelix) (ODB Formulary)

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B - Drug Regimen

Initial Dose

degarelix[1]	240 mg	Subcut	Day 1 of Month 1

(give as 2 x 120 mg injections, at 40 mg/mL)

Maintenance Dose (Beginning 1 month after the starting dose)

degarelix[1]	80 mg	Subcut	Once every month

(at 20 mg/mL)

(1) The concentrations recommended above should be used, since the pharmacokinetics of degarelix are concentration-dependent.

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C - Cycle Frequency

REPEAT MONTHLY

For a total of 12 months of treatment unless disease progression or unacceptable toxicity occurs.

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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.

Dosage with toxicity

Worst Toxicity / Counts (x 10^9/L) in previous cycle		**Worst Toxicity / Counts (x 10^9/L) in previous cycle**	**degarelix (% previous dose)**	**degarelix (% previous dose)**	**[Drug C] (% previous dose)**
ANC <1.5	Or	Platelet < 100	Hold *		
Febrile Neutropenia Or ANC < 0.5 for ≥ 5-7 d	Or	Thrombocytopenic bleeding Or Platelets < 25	Hold *, then 75%		
ANC ≥ 1.5	And	Platelet ≥ 100	100%		
Cardiotoxicity**			Discontinue		
Grade 3 related organ / non-hematologic			*75% for suspect drug(s)		
Grade 4 related organ / non-hematologic			Discontinue		

*Do not start new cycle until toxicities have recovered to ≤ grade 2, platelets ≥ 100 x 10^9/L, and ANC ≥ 1.5 x 10^9/L.

**including any signs and symptoms of heart failure, greater than 10% decline in LVEF to below the lower limit of normal, a greater than 20% decline in LVEF from any level, or LVEF ≤ 45%.

Hepatic Impairment

Although drug exposure is 10-18% lower in mild to moderate hepatic impairment, no dosage adjustment is required in these patients. Exercise caution in patients with severe hepatic impairment as no studies have been conducted in this population.

Renal Impairment

Drug clearance decreases by 23% in patients with moderate renal impairment (< 50 mL/min); however, no dosage adjustment is required in mild to moderate renal impairment. Exercise caution in patients with severe renal impairment as there is insufficient data available in this population.

Dosage in the Elderly

No dose adjustment required.

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F - Adverse Effects

Refer to degarelix drug monograph for additional details of adverse effects.

Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Injection site reaction (may be severe) • Androgen withdrawal symptoms	• QT interval prolonged • ↑ LFTs	• Arterial thromboembolism • Atrioventricular block • Hypersensitivity

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G - Interactions

Refer to degarelix drug monograph for additional details.

- Caution is advised when administered with drugs that may prolong QT. If concomitant use is unavoidable, close monitoring for evidence of QT prolongation or other alterations of cardiac rhythm is required.

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H - Drug Administration and Special Precautions

Refer to degarelix drug monograph for additional details.

Administration:

- For **subcutaneous** injection in the abdomen, do not inject into a vein or into muscle.
- Reconstitute using sterile water for injection (SWI) as directed in the product monograph. Reconstitution procedure may take up to 15 minutes.
- The concentrations recommended in the dosing section for starting and maintenance doses should be used, since the pharmacokinetics of degarelix are strongly concentration-dependent.
- Gloves should be worn during preparation and administration.
- Ensure injection site is free of pressure from belts, waistbands, other clothing, or ribs.
- Rotate injection site.
- Begin maintenance dose 28 days after initial loading dose.

Contraindications:

- Patients who have hypersensitivity to degarelix or to any of its excipients.

Other Warnings/Precautions:

- Fatigue and dizziness are common adverse reactions with degarelix and caution must be exercised with driving and operating machines.
- Long-term androgen deprivation prolongs the QT interval. Although a thorough QT study showed that there was no intrinsic effect of degarelix on heart rate, QT/QTc, PR intervals, QRS duration, or T or U waver morphology in healthy men, caution should be exercised in patients with congenital long QT syndrome, electrolyte abnormalities, congestive heart failure, and in patients taking antiarrhythmic medications.

Pregnancy and Lactation:

- This regimen is **contraindicated** in patients who are or may become pregnant. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Degarelix is **only indicated in patients with prostate cancer**. There are no data on the presence of degarelix in human milk.
- Fertility effects: Probable

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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

- ECG: Baseline and as clinically indicated
- Liver function tests: Baseline and as clinically indicated
- Electrolytes (calcium, magnesium, potassium, sodium): Baseline and as clinically indicated
- Creatinine: Baseline and as clinically indicated
- Testosterone concentrations: In patients with hepatic impairment: monthly until medical castration is achieved then every 2 months
- Blood sugar: Baseline and as clinically indicated
- Clinical toxicity assessment for local reactions, diabetes, osteoporosis, cardiovascular changes, hot flashes: at each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version.

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J - Administrative Information

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

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K - References

Degarelix Drug Monograph, Ontario Health (Cancer Care Ontario).

Gittelman M, Pommerville PJ, Persson B-E, et al. A 1-year, open-label, randomized phase II dose finding study of degarelix for the treatment of prostate cancer in North America. J Urol 2008;180(5):1986-92.

Klotz L, Boccon-Gibod L, Shore ND, et al. The efficacy and safety of degarelix: a 12-month, comparative, randomized, open-label, parallel-group phase III study in patients with prostate cancer. BJU Int 2008;102(11):1531-8.

Van Poppel H, Tombal B, de la Rosette JJ, et al. Degarelix: a novel gonadotropin-releasing hormone (GnRH) receptor blocker-results from a 1-yr, multicentre, randomised, phase 2 dosage-finding study in the treatment of prostate cancer. Eur Urol 2008;54(4):805-15.

February 2025 Updated pregnancy/lactation section

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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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Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

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