

Regimen Monograph

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A - Regimen Name

FLTM Regimen

Flutamide

Disease Site Genitourinary - Prostate**Intent** 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

- Metastatic prostate cancer (Stage D2) in conjunction with LHRH agonist or orchiectomy
- Stage B₂ or C prostate cancer prior to or during external beam radiotherapy in combination with LHRH agonist

Supplementary Public Funding [flutamide](#)
ODB - General Benefit ([ODB Formulary](#))[back to top](#)

B - Drug Regimen

[flutamide](#) 250 mg PO Every 8 hours (TID)
(Outpatient prescription in 250 mg tablets)

Flutamide should be used in combination with orchiectomy or with an LHRH agonist. Start simultaneously / 24 hours prior to LHRH agonist. If patient is receiving external beam radiation, start flutamide 8 weeks prior to radiation and continue throughout radiation treatment.

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C - Cycle Frequency**CONTINUOUS TREATMENT**

Until disease progression or unacceptable toxicity

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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.

Dosage with toxicity

Dosage in myelosuppression: No adjustment required

Hepatic Impairment

Discontinue flutamide if jaundice or liver transaminases $\geq 2-3 \times$ ULN.

Renal Impairment

No adjustment required; slightly prolonged half-life in patients with CrCl < 29 mL/min. Not significantly removed by hemodialysis.

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F - Adverse Effects

Refer to [flutamide](#) drug monograph(s) for additional details of adverse effects. The following table contains adverse effects reported in combination use with a LHRH agonist.

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
<ul style="list-style-type: none"> • Androgen deprivation symptoms • Diarrhea • Nausea/vomiting 	<ul style="list-style-type: none"> • Cardiotoxicity • Arterial thromboembolism • Prolonged QT • Venous thromboembolism • Osteopenia/Osteoporosis • Rash • Hemolysis • ↑ LFTs • Secondary malignancies • Pneumonitis • Autoimmune - lupus-like syndrome

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G - Interactions

Refer to [flutamide](#) drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to [flutamide](#) drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Blood glucose, HgA1c; in diabetic patients or patients at risk of hyperglycemia; regular
- ECG and electrolyte for patients at risk of QT prolongation
- Liver function tests; baseline, monthly for the first 4 months, then periodically and as clinically indicated
- Clinical evaluation for symptoms of hypogonadism, gynecomastia, osteoporosis, hyperglycemia, cardiovascular and GI effects; regular
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

Suggested Clinical Monitoring

- INR, in patients on anticoagulants; regular
- Methemoglobin concentrations in at risk patients (e.g. G6PD deficiency, hemoglobin M disease)

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Crawford ED, Eisenberger MA, McLeod DG, et al. A controlled trial of leuprolide with and without flutamide in prostatic carcinoma. N Engl J Med 1989;321(7):419-24.

Denis LJ, Carneiro de Moura JL, Bono J, et al. Goserelin acetate and flutamide versus bilateral orchiectomy : A phase III EORTC trial (30853). Urology 1993;42(2):119-29.

Eisenberger MA, Blumenstein BA, Crawford ED,, et al. Bilateral orchiectomy with or without flutamide for metastatic prostate cancer. N Engl J Med 1998;339(15):1036-42.

October 2016 Replaced regimen category with evidence-informed

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M - Disclaimer

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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