**Regimen Monograph**

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Dose Modifications | Adverse Effects | Interactions | Drug Administration and Special Precautions | Recommended Clinical Monitoring | Administrative Information | References | Other Notes | Disclaimer

## A - Regimen Name

# NLTM Regimen

**Nilutamide**

| | |
|---|---|
| **Disease Site** | Genitourinary - Prostate |
| **Intent** | Palliative |
| **Regimen Category** | **Evidence-Informed :**<br>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** | Treatment of metastatic prostatic carcinoma (Stage D2) in conjunction with surgical / medical castration |
| **Supplementary Public Funding** | **niLUTAmide**<br>ODB - General Benefit (niLUTAmide) (ODB Formulary) |

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## B - Drug Regimen

| | | | |
|---|---|---|---|
| **niLUTAmide** | 300 mg | PO | Daily during the first month (days 1 to 30*) |
| then | | | |

| | | | |
|---|---|---|---|
| **niLUTAmide** | 150 mg | PO | Daily thereafter |

(Outpatient prescription in 50 mg or 150 mg tablets)
*may start maintenance earlier should intolerance occur

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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**

| Toxicity | Dose Adjustment |
|---|---|
| Myelosuppression | No adjustment required |
| Suspected pneumonitis | Hold, investigate and treat appropriately; discontinue if confirmed |
| QT prolongation | Discontinue |

**Hepatic Impairment**

If transaminases >2-3x upper limit of normal, interrupt treatment and monitor liver function closely. Discontinue if severe hepatic impairment.

**Renal Impairment**

No adjustment required.

**Dosage in the elderly**

No adjustment required.

**Dosage with ethnicity**

A higher rate of interstitial pneumonitis and elevated transaminases were reported in Japanese patients. Use with caution when treating Asian patients.

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## F - Adverse Effects

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

| Less common side effects (10-24%) | Uncommon (< 10%), but may be severe or life-threatening |
|---|---|
| • Androgen deprivation symptoms (e.g. hot flashes, mood changes, erectile dysfunction)<br>• Eye disorders (e.g. reduced light to dark adaptation) | • Cardiotoxicity<br>• QT prolongation<br>• Arterial thromboembolism<br>• Pneumonitis<br>• Hepatic failure<br>• Bone loss, osteoporosis<br>• Aplastic anemia |

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## G - Interactions

Refer to nilutamide drug monograph(s) for additional details

- Avoid alcohol as a potential disulfiram-like reaction may occur
- Use with caution and monitor closely with drugs that increase the QT interval
- Nilutamide is a weak inhibitor of CYP2C19. Use with caution and monitor with drugs that have a narrow therapeutic index (e.g. warfarin, phenytoin)

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## H - Drug Administration and Special Precautions

Refer to nilutamide drug monograph(s) for additional details

**Administration:**

- Take tablet(s) by mouth, before breakfast.
- Avoid alcoholic beverages during treatment.
- If a dose is missed, the next dose should be taken at the usual time. A double dose should not be taken to make up for missed doses.
- Store between 15 to 30°C.

**Contraindications:**

- Patients with known hypersensitivity to the drug or to any constituents of the drug product
- Patients with severe hepatic dysfunction or with severe respiratory insufficiency.
- Nilutamide is also contraindicated in women and children.
- Contains lactose and should not be used in patients with hereditary galactose/glucose/lactase disorders.

**Other Warnings/Precautions:**

- Patients should be advised regarding impairment of light adaptation if they plan to operate a vehicle or machinery.
- Nilutamide should not be administered to patients with congenital long QT syndrome, and should be discontinued in patients who develop QT prolongation.

**Pregnancy and Lactation:**

- Nilutamide should not be used by women. In the laboratory, this drug may harm or affect the embryos of offspring of animals exposed to it.
- If there is a chance of pregnancy in a female partner, adequate contraception should be used by both sexes during treatment, and for at least 6 months after the last dose (general recommendation).

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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 and electrolytes at baseline; also regularly for patients at risk of QT prolongation
- Chest X-ray +/- pulmonary function tests; baseline and as clinically indicated
- Liver function tests; baseline and as clinically indicated
- Blood glucose, HgA1c especially in diabetic patients; baseline and at each visit
- Clinical evaluation for androgen deprivation symptoms, ocular and respiratory effects, cardiovascular effects; at each visit

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

Suggested Clinical Monitoring

- INR, in patients on warfarin; baseline and as clinically indicated

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## J - Administrative Information

Outpatient prescription for home administration

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## K - References

Bertagna C, de Géry A, Hucher M, et al. Efficacy of the combination of nilutamide plus orchiectomy in patients with metastatic prostate cancer. A meta-analysis of seven randomized double-blind trials (1056 patients). British Journal of Urology 1994;73:396-402.

Janknegt RA, Abbou CC, Bartoletti R, et al. Orchiectomy and nilutamide or placebo as treatment of metastatic prostatic cancer in a multinational double-blind randomized trial. J Urol 1993;149(1):77-82.

Nilutamide drug monograph, Cancer Care Ontario.

**September 2018** Updated adverse effects, administration and monitoring

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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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