Regimen Monograph

A - Regimen Name

MXNTPRED Regimen

mitoXANTRONE-Prednisone

Disease Site	Genitourinary - Prostate (Metastatic - Stage D)
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	Treatment of castration-resistant prostate cancer
Supplementary Public Funding	**prednisone** ODB - General Benefit

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B - Drug Regimen

mitoXANTRONE (Round to nearest 1mg)	12-14 mg /m²	IV	Day 1
prednisone	5 mg	PO	BID

(Outpatient prescription in multiples of 5mg tablets)

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

Until disease progression

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

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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 are in use at some centres.
Hematologic Toxicities: See Appendix 6 for general recommendations.

Dosage with toxicity

Dosage in myelosuppression:
Modify according to protocol by which patient is being treated; if no guidelines available refer to Appendix 6 "Dosage Modification Hematologic and Non-Hematologic Toxicities".

Suggested modifications are:

WBC and Platelet Nadir ($x 10^9/L$)			Time to Recovery	Subsequent Dose
WBC		Platelets		
> 1.5	AND	> 50	≤ 21 days	No change. May increase by 2mg/m^2 if inadequate myelosuppression
			> 21 days	Hold until recovery. Do not increase dose
1 to 1.499	OR	25 to 49		Reduce dose by 2mg/m^2
< 1	OR	< 25		Reduce dose by 4mg/m^2

Hepatic Impairment

Hepatic Impairment	Mitoxantrone Dose
Mild-Moderate	↓ 50%
Bilirubin > 2-3 x ULN	Hold
Severe	Hold

Renal Impairment

No adjustment required

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F - Adverse Effects

Refer to mitoXANTrone, prednisone drug monograph(s) for additional details of adverse effects

Most frequently occurring adverse effects

- Nausea and vomiting
- Cardiotoxicity
- Myelosuppression
- Blue-green urine

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G - Interactions

Refer to mitoXANTrone, prednisone drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to mitoXANTrone, prednisone drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Clinical toxicity (including cardiotoxicity) assessment
- CBC before each cycle
- Baseline and regular liver & renal function tests
- Baseline and regular cardiac examination for patients with cardiac risk factors (including prior therapy with Epirubicin, Doxorubicin and other cardiotoxic drugs), and cumulative mitoxantrone doses > 140mg/m^2
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

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J - Administrative Information

Approximate Patient Visit	0.5 hour
Pharmacy Workload (average time per visit)	18.198 minutes
Nursing Workload (average time per visit)	43.667 minutes

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K - References

Berthold DR, Pond GR, Soban F et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer: updated survival in the TAX 327 study. JCO 2008; 26(2): 242-5.

Kantoff PW, Halabi S, Conaway M, et. al. Hydrocortisone with or without mitoxantrone in men with hormone-refractory prostate cancer: results of the cancer and leukemia group B9182 study. J Clin Oncol 1999 Aug; 17(8): 2506-13

Tannock IF, de Wit R, Berry W, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med 2004; 351(15): 1502-12.

Tannock IF, Osoba D, Stockler MR, et. al. Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer: a Canadian randomized trial with palliative end points. J Clin Oncol 1996 June; 14(6): 1756-64.

PEBC Advice Documents or Guidelines

- Systemic Therapy in Men with Metastatic Castration-Resistant Prostate Cancer

April 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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