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

DARODOCE Regimen

Darolutamide-DOCEtaxel

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.

This **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). 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.

Rationale and Uses

For the treatment of metastatic hormone-sensitive prostate cancer

Supplementary Public Funding	**darolutamide** Exceptional Access Program (darolutamide - For the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel) (EAP Website)

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B - Drug Regimen

DOCEtaxel	75 mg /m²	IV	Day 1
darolutamide	600 mg	PO	BID, Days 1 to 21

Start docetaxel within 6 weeks after initiating darolutamide.

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog unless they have had a bilateral orchiectomy.

Docetaxel can be administered in combination with prednisone at the discretion of the physician (Smith et al., 2022)

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C - Cycle Frequency

REPEAT EVERY 21 DAYS

For a usual total of 6 cycles, followed by darolutamide (DARO(MNT)) unless disease progression or unacceptable toxicity occurs

Continue with darolutamide if docetaxel is delayed, held, or discontinued before completion of 6 cycles.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Low

- Also refer to CCO Antiemetic Summary.

Screen for hepatitis B virus in all cancer patients starting systemic treatment. Refer to the hepatitis B virus screening and management guideline.

DOCEtaxel Premedications (prophylaxis for infusion reaction):

- Dexamethasone* 8 mg PO BID for 3 days, starting 1-day pre-infusion†

An alternative for patients with prostate cancer being treated with prednisone:

- Dexamethasone* 8 mg PO 12 hours, 3 hours, and 1 hour pre-infusion.

*Do **not** discontinue dexamethasone, even in the absence of an IR, due to the benefits on other adverse effects (e.g. pain and edema).

†Dexamethasone 10-20 mg IV can be given if patient forgot to take oral doses.

Other Supportive Care:

- Optimize management of cardiovascular risk factors (e.g., hypertension, diabetes, or dyslipidemia).

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J - Administrative Information

Darolutamide: Outpatient prescription for home administration

Approximate Patient Visit	2 hours
Pharmacy Workload (average time per visit)	23.936 minutes
Nursing Workload (average time per visit)	54.167 minutes

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K - References

CADTH reimbursement recommendation: Darolutamide (for the treatment of patients with metastatic castration-sensitive prostate cancer in combination with docetaxel). January 2023.

Darolutamide drug monograph. Ontario Health (Cancer Care Ontario).

Docetaxel drug monograph. Ontario Health (Cancer Care Ontario).

Smith MR, Hussain M, Saad F, et al. Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer. N Engl J Med. 2022 Mar 24;386(12):1132-1142. doi: 10.1056/NEJMoa2119115.

March 2024 Added darolutamide funding information

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M - Disclaimer

Regimen Abstracts

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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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last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.

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