

## 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

**DOCE Regimen**

DOCEtaxel

**Disease Site**      Genitourinary - Bladder / Urothelial

**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 advanced or metastatic transitional cell carcinoma, in patients who had failed to respond or relapsed on prior cisplatin-based chemotherapy

[back to top](#)

## B - Drug Regimen

**[DOCEtaxel](#)**75 mg /m<sup>2</sup>

IV

Day 1

[back to top](#)

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## C - Cycle Frequency

### REPEAT EVERY 21 DAYS

Until disease progression or unacceptable toxicity.

[back to top](#)

## D - Premedication and Supportive Measures

**Antiemetic Regimen:** Low

### Other Supportive Care:

Also refer to [CCO Antiemetic Summary](#)

### **Pre-medications (prophylaxis for infusion reaction):**

- Dexamethasone\* 8 mg PO BID for 3 days, starting 1-day pre-infusion<sup>†</sup>

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

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

[back to top](#)

**E - Dose Modifications**

Doses should be modified according to the protocol by which the patient is being treated.

**Dosage with toxicity**

Toxicity (worst in previous cycle)	Docetaxel dose*
Febrile neutropenia / Grade 4 ANC ≥ 7 d	75% of previous dose
Grade 3 skin/ neuro/ major organ/ non-hematologic toxicity	75% of previous dose
Any occurrence of cystoid macular edema	Hold and investigate; refer patient promptly an ophthalmic examination. Discontinue if confirmed.
Grade 4 skin/ neuro/ major organ/ non-hematologic toxicity OR Recurrence of Grade 3 toxicity after prior dose reduction	Discontinue
* Do not retreat until ANC ≥ 1.5 x 10 <sup>9</sup> /L, platelets ≥ 100 x 10 <sup>9</sup> /L, and toxicity ≤ grade 2.	

**Management of Infusion-related reactions:**

Also refer to the CCO guideline for detailed description of [Management of Cancer Medication-Related Infusion Reactions](#).

Grade	Management	Re-challenge
1 or 2	<ul style="list-style-type: none"> <li>Stop or slow the infusion rate.</li> <li>Manage the symptoms.</li> </ul> <p><b>Restart:</b></p> <ul style="list-style-type: none"> <li>After symptom resolution, restart with pre-medications ± reduced infusion rate.</li> </ul>	<ul style="list-style-type: none"> <li>Consider re-challenge with pre-medications and at a reduced infusion rate.</li> <li>After 2 subsequent IRs, replace with a different taxane. Give intensified pre-medications and reduce the infusion rate.</li> <li>May consider adding oral montelukast ± oral acetylsalicylic acid.</li> </ul>
3 or 4	<ul style="list-style-type: none"> <li>Stop treatment.</li> <li>Aggressively manage symptoms.</li> </ul>	<ul style="list-style-type: none"> <li>Re-challenge is discouraged, especially if vital symptoms have been</li> </ul>

		<p>affected.</p> <ul style="list-style-type: none"> <li>• Consider desensitization if therapy is necessary.</li> <li>• There is insufficient evidence to recommend substitution with another taxane at re-challenge.</li> <li>• High cross-reactivity rates have been reported.</li> </ul>	
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### **Hepatic Impairment**

Patients with hepatic impairment have a higher risk of severe adverse effects, including fatal gastrointestinal hemorrhage, sepsis and myelosuppression.

<b>Bilirubin</b>		<b>AST and/or ALT</b>		<b>Alkaline Phosphatase</b>	<b>Docetaxel dose</b>
> ULN	AND	Any	AND	Any	Do not treat. Discontinue if treatment already started.
Any	AND	> 1.5 X ULN	AND	> 2.5 x ULN	

### **Renal Impairment**

No adjustment required.

### **Dosage in the Elderly**

No adjustment required, but caution should be exercised in elderly patients with poor performance status who are receiving docetaxel.

[back to top](#)

## **F - Adverse Effects**

Refer to [DOCEtaxel](#) drug monograph(s) for additional details of adverse effects.

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
<ul style="list-style-type: none"> <li>• Fatigue</li> <li>• Myelosuppression +/- bleeding (may be severe)</li> <li>• Alopecia (may be permanent)</li> </ul>	<ul style="list-style-type: none"> <li>• Edema (may be severe)</li> <li>• Neuropathy (may be severe)</li> <li>• Nausea/vomiting</li> <li>• Mucositis (may be severe)</li> <li>• Diarrhea (may be severe, especially with neutropenia)</li> <li>• Rash (may be severe)</li> <li>• Nail disorder</li> </ul>	<ul style="list-style-type: none"> <li>• Hypersensitivity (may be severe)</li> <li>• Musculoskeletal pain</li> </ul>	<ul style="list-style-type: none"> <li>• Arrhythmia</li> <li>• Cardiotoxicity</li> <li>• Arterial thromboembolism</li> <li>• Venous thromboembolism</li> <li>• GI obstruction / perforation</li> <li>• Radiation and injection site recall reaction</li> <li>• ↑ LFTs</li> <li>• Seizure</li> <li>• Cystoid macular edema</li> <li>• Tear duct obstruction</li> <li>• Pneumonitis/Adult Respiratory Distress Syndrome (ARDS)</li> <li>• Disseminated intravascular coagulation (DIC)</li> <li>• Secondary malignancies</li> <li>• Hand-foot syndrome</li> <li>• Nephrotoxicity</li> </ul>

[back to top](#)

## G - Interactions

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

- Avoid concomitant use with CYP3A4 inhibitors. If must use together, consider decreasing docetaxel dose (50% for strong inhibitors).
- Caution with CYP3A4 inducers and substrates
- Avoid concurrent use with dronedarone

[back to top](#)

## H - Drug Administration and Special Precautions

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

### **Administration:**

- Refer to the respective product monographs for preparation instructions. Mix in 250mL D5W or NS to a maximum concentration of 0.3-0.74 mg/mL. For doses over 200mg, use a larger volume of the infusion vehicle so the maximum concentration is not exceeded.
- Infuse through main IV line over 1 hour.
- In order to minimize patients' exposure to DEHP leaching from PVC bags or sets, use polyolefin or polypropylene infusion bags and polyethylene-lined administration sets.
- To minimize hypersensitivity reactions, docetaxel infusion should be started at a slow rate, then increased incrementally to planned rate.
- Monitor patient for signs of alcohol intoxication (due to alcohol content in formulation) during and after the infusion.
- Injection site recall reactions (recurrence of skin reaction at a previous extravasation site after docetaxel is administered at a different site) have been observed.

Also refer to the CCO guideline for detailed description of [Management of Cancer Medication-Related Infusion Reactions](#).

### **Contraindications:**

- Patients who have a history of severe hypersensitivity reactions to docetaxel, to other drugs formulated with polysorbate 80 or polyethylene glycol 300, or to any components of the formulation
- Patients with baseline neutrophil counts of  $<1.5 \times 10^9/L$
- Patients with severe liver impairment

### **Other Warnings/Precautions:**

- Patients with:

- 
- bilirubin > ULN or
  - AST and/or ALT > 1.5 x ULN and ALP > 2.5 x ULN or
  - ANC < 1.5 x 10<sup>9</sup>/L
  - (refer to dose modifications section)
  - Use with caution in patients with pre-existing effusions or ascites.
  - Use with caution in patients who have hypersensitivity to paclitaxel.
  - Docetaxel contains ethanol ( $\pm 1\text{g}/\text{m}^2$ ; refer to respective product monographs) and may cause drowsiness. Patients should be cautioned regarding driving and the use of machinery immediately after receiving the infusion. Ethanol may be harmful to patients at risk of adverse effects such as those with alcoholism, liver disease, epilepsy and children. Cases of alcohol intoxication have been reported.

**Pregnancy/Lactation:**

- Docetaxel is **contraindicated in pregnancy and lactation**. Adequate contraception must be used by both sexes, during docetaxel treatment and for at least **6 months** after the last dose. Fertility may be affected.

[back to top](#)

## 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

- CBC, including nadir counts; baseline and before each dose
- Liver function tests; baseline and before each dose
- Clinical toxicity assessment of infection, bleeding, neurotoxicity, fluid retention, hypersensitivity, lethargy, cutaneous reactions, thromboembolism, musculoskeletal pain, cardiovascular, ophthalmic, GI or respiratory effects, enterocolitis with neutropenia; at each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

[back to top](#)

## J - Administrative Information

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

[back to top](#)

## K - References

Docetaxel drug monograph, Cancer Care Ontario.

Logothetis C, Millikan R. Docetaxel in the management of advanced or metastatic urothelial tract cancer. *Oncology (Williston Park)* 2002 Jun;16(6 Suppl 6):107-11.

McCaffrey JA, Hilton S, Mazumdar M, et al. Phase II trial of docetaxel in patients with advanced or metastatic transitional-cell carcinoma. *J Clin Oncol*;15(5):1853-7.

**July 2020** Updated Drug Administration section

[back to top](#)



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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.*

*The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of 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.*

*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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[back to top](#)