

## Regimen Monograph

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## A - Regimen Name

# DOCE Regimen

DOCEtaxel

**Disease Site** Head and Neck

**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** For the treatment of advanced or recurrent squamous cell cancer of the head and neck.

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**B - Drug Regimen****[DOCEtaxel](#)**75 to 100 mg /m<sup>2</sup> IV

Day 1

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Until disease progression or unacceptable toxicity

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- 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.

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**E - Dose Modifications**

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

Patients should not be treated until they have recovered from prior toxicity and have acceptable blood counts (ANC  $\geq 1.5 \times 10^9/L$  and platelets  $\geq 100 \times 10^9/L$ ).

**Dosage with toxicity**

<b>Toxicity (worst in previous cycle)</b>	<b>Docetaxel dose*</b>
Febrile neutropenia / Grade 4 ANC $\geq 7$ 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  OR  Any Severe Cutaneous Adverse Reactions (SCARs) (e.g. Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Acute generalized exanthematous pustulosis (AGEP))	Discontinue
* Do not retreat until ANC $\geq 1.5 \times 10^9/L$ , platelets $\geq 100 \times 10^9/L$ , and non-hematologic / organ toxicity $\leq$ 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 affected.</li> <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>

**Hepatic Impairment**

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

Bilirubin		AST and/or ALT		Alkaline Phosphatase	Docetaxel dose
> 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.

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**F - Adverse Effects**

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

<b>Very common (≥ 50%)</b>	<b>Common (25-49%)</b>	<b>Less common (10-24%)</b>	<b>Uncommon (&lt; 10%), but may be severe or life-threatening</b>
<ul style="list-style-type: none"> <li>• Alopecia (rarely permanent)</li> <li>• Myelosuppression +/- bleeding (may be severe)</li> <li>• Fatigue</li> </ul>	<ul style="list-style-type: none"> <li>• Neuropathy (may be severe)</li> <li>• Rash (may be severe)</li> <li>• Edema (may be severe)</li> <li>• Mucositis (may be severe)</li> <li>• Diarrhea (may be severe, especially with neutropenia)</li> <li>• Nausea/vomiting</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>• Injection site reaction</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>• Stevens-Johnson syndrome</li> <li>• Toxic epidermal syndrome</li> <li>• Acute generalized exanthematous pustulosis</li> </ul>

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## 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).
- Avoid concurrent use with dronedarone.

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## 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. Slowing the infusion rate during administration may help resolve symptoms.
- 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](#).

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**Contraindications:**

- Patients who have a history of 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:**

- Use with caution in patients with pre-existing effusions or ascites.
- Use with caution in patients who have hypersensitivity to paclitaxel. Patients who have previously experienced a hypersensitivity reaction to paclitaxel may develop a potentially fatal hypersensitivity reaction to docetaxel.
- Docetaxel contains ethanol (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** for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is **contraindicated** during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility may be affected, especially in males.

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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.

Refer to the [hepatitis B virus screening and management](#) guideline for monitoring during and after treatment.

### 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, secondary malignancies, 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](#)

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## 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

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## K - References

Catimel G, Verweij J, Mattijssen V, et al. Docetaxel (Taxotere): an active drug for the treatment of patients with advanced squamous cell carcinoma of the head and neck. EORTC Early Clinical Trials Group. Ann Oncol 1994;5(6):533-7.

Couteau C, Chouaki N, Leyvraz S, et al. A phase II study of docetaxel in patients with metastatic squamous cell carcinoma of the head and neck. Br J Cancer. 1999 Oct;81(3):457-62.

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

Dreyfuss AI, Clark JR, Norris CM, et al. Docetaxel: an active drug for squamous cell carcinoma of the head and neck. J Clin Oncol 1996;14(5):1672-8.

Limaye S, Riley S, Zhao S, et al. A randomized phase II study of docetaxel with or without vandetanib in recurrent or metastatic squamous cell carcinoma of head and neck (SCCHN). Oral Oncol. 2013 Aug;49(8):835-41.

**May 2024** Modified Dose modifications, Adverse effects, Interactions, Warnings/Precautions, Pregnancy/lactation, and Monitoring sections

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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*

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*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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