DOCEtaxel Monotherapy $75mg/m^2$ – 21 day cycle

**INDICATIONS FOR USE:**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>*Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of prior chemotherapy</td>
<td>C34</td>
<td>00203a</td>
<td>Hospital</td>
</tr>
<tr>
<td>First line in high risk non metastatic castration sensitive prostate cancer</td>
<td>C61</td>
<td>00203b</td>
<td>Hospital</td>
</tr>
<tr>
<td>First line in metastatic castration sensitive prostate cancer</td>
<td>C61</td>
<td>00203c</td>
<td>Hospital</td>
</tr>
<tr>
<td>Advanced or metastatic adenocarcinoma of the stomach or gastro-oesophageal junction in patients who have progressed during or within 6 months after treatment with a platinum-fluoropyrimidine combination</td>
<td>C15</td>
<td>00203d</td>
<td>Hospital</td>
</tr>
<tr>
<td>Treatment of Relapsed/Progressing primary peritoneal carcinoma</td>
<td>C48</td>
<td>00203e</td>
<td>Hospital</td>
</tr>
<tr>
<td>Treatment of Relapsed/Progressing Epithelial Ovarian carcinoma</td>
<td>C56</td>
<td>00203f</td>
<td>Hospital</td>
</tr>
<tr>
<td>Treatment of Relapsed/Progressing Fallopian Tube Carcinoma</td>
<td>C57</td>
<td>00203g</td>
<td>Hospital</td>
</tr>
<tr>
<td>Treatment of advanced breast cancer</td>
<td>C50</td>
<td>00203h</td>
<td>Hospital</td>
</tr>
</tbody>
</table>

*If the reimbursement status is not defined, the indication has yet to be assessed through the formal HSE reimbursement process.*

**TREATMENT:**
The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patient's individual clinical circumstances.

**NSCLC:** Treatment administered every 21 days, for a maximum of 6 cycles or until disease progression or unacceptable toxicity develops.

For all other indications **203b-203h** treatment is be administered every 21 days, until disease progression or unacceptable toxicity develops.

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DOCEtaxel</td>
<td>75mg/m²</td>
<td>IV infusion</td>
<td>*250ml 0.9% sodium chloride over 60min</td>
<td>Repeat every 21 days</td>
</tr>
</tbody>
</table>

*75-185mg dose use 250mL infusion bag. For doses >185mg use 500mL infusion bag. Use non-PVC equipment.

**ELIGIBILITY:**
- Indications as above
- ECOG 0-2

The information contained in this document is a statement of consensus of NCCP and ISMO or IHS professionals regarding their views of currently accepted approaches to treatment. Any clinician seeking to apply or consult these documents is expected to use independent medical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. Use of these documents is the responsibility of the prescribing clinician. and is subject to HSE’s terms of use available at [http://www.hse.ie/eng/Disclaimer](http://www.hse.ie/eng/Disclaimer).

This information is valid only on the day of printing, for any updates please check [www.hse.ie/NCCPchemoregimens](http://www.hse.ie/NCCPchemoregimens).
EXCLUSIONS:
- Hypersensitivity to DOCEtaxel or to any of the excipients
- Severe liver impairment
- Baseline neutrophil count < 1.5 x 10^9 cells/L

PRESCRIPTIVE AUTHORITY:
The treatment plan must be initiated by a Consultant Medical Oncologist.

TESTS:
Baseline tests:
- FBC, renal and liver profile

Regular tests:
- FBC, renal and liver profile *
  *See Adverse Effects/Regimen specific complications for guidelines regarding hepatic dysfunction

Disease monitoring:
Disease monitoring should be in line with the patient’s treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:
- Any dose modification should be discussed with a Consultant

Haematological:
**Table 1: Dose modification of DOCEtaxel for haematological toxicity**

<table>
<thead>
<tr>
<th>ANC (x10⁹/L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1.5</td>
<td>75mg/m²</td>
</tr>
<tr>
<td>0.5 to less than 1.5</td>
<td>Delay treatment until recovery</td>
</tr>
<tr>
<td>Febrile neutropenia or &lt;0.5 for more than 1 week</td>
<td>Reduce dose from 75 to 60mg/m². Discontinue treatment if continues at lower dose.</td>
</tr>
</tbody>
</table>
Renal and Hepatic Impairment:
No data available in patients with severely impaired renal function

<table>
<thead>
<tr>
<th>Alkaline Phosphatase</th>
<th>AST and/or ALT</th>
<th>Serum Bilirubin</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 2.5 ULN and</td>
<td>&gt; 1.5 ULN</td>
<td></td>
<td>75 mg/m²</td>
</tr>
<tr>
<td>&gt; 6 ULN and/or</td>
<td>&gt; 3.5 ULN (AST and ALT) and &gt; ULN</td>
<td>Stop treatment unless strictly indicated and should be discussed with a Consultant.</td>
<td></td>
</tr>
</tbody>
</table>

Management of adverse events:

<table>
<thead>
<tr>
<th>Adverse reactions</th>
<th>Recommended dose modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3 skin reaction</td>
<td>Decrease dose to 60mg/m²</td>
</tr>
<tr>
<td>Grade &gt;2 peripheral neuropathy</td>
<td>If the patient continues to experience these reactions at 60 mg/m², the treatment should be discontinued</td>
</tr>
<tr>
<td>Grade 3 or 4 stomatitis</td>
<td></td>
</tr>
</tbody>
</table>

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Low (Refer to local policy).

PREMEDICATIONS:

- Dexamethasone 8 mg PO twice daily for 3 days, starting one day prior to each DOCetaxel administration unless contraindicated. Patient must receive minimum of 3 doses pre-treatment.
- Consideration may be given, at the discretion of the prescribing consultant, to the use of a single dose of dexamethasone 20mg IV immediately before chemotherapy where patients have missed taking the oral premedication dexamethasone as recommended by the manufacturer

OTHER SUPPORTIVE CARE:

- Prophylactic G-CSF may be used to mitigate the risk of haematological toxicities.

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS
The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- Fluid Retention: Dexamethasone premedication must be given to reduce the incidence and severity of fluid retention. It can also reduce the severity of the hypersensitivity reaction.
- Neutropenic Enterocolitis: A number of cases of neutropenic enterocolitis have been reported in patients treated with DOCetaxel in France (5). This is a known and rare side effect of DOCetaxel which may affect up to one in 1,000 people
- Hypersensitivity Reactions: Patients should be observed closely for hypersensitivity reactions especially during the first and second infusions. Hypersensitivity reactions may occur within a few minutes following the initiation of the infusion of DOCetaxel, thus facilities for the treatment of hypotension and bronchospasm should be available. If hypersensitivity reactions occur, minor symptoms such as flushing or localized cutaneous reactions do not require interruption of therapy. However, severe reactions, such as severe hypotension, bronchospasm or generalised...
rash/erythema require immediate discontinuation of DOCEtaxel and appropriate therapy. Patients who have developed severe hypersensitivity reactions should not be re-challenged with DOCEtaxel.

**Extravasation:** DOCEtaxel causes pain and tissue necrosis if extravasated. (Refer to local extravasation guidelines).

**Neutropenia:** Most frequent adverse reaction. Fever or other evidence of infection must be assessed promptly and treated aggressively. DOCEtaxel should be administered when the neutrophil count is > 1.5x10^9 cells/L.

**Hepatic Dysfunction:** DOCEtaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST) may lead to increased toxicity and usually requires a dose reduction

**DRUG INTERACTIONS:**
- Risk of drug interactions causing increased concentrations of DOCEtaxel with CYP3A inhibitors. Patients should also be counselled with regard to consumption of grapefruit juice.
- Risk of drug interactions causing decreased concentrations of DOCEtaxel with CYP3A inducers.
- Current drug interaction databases should be consulted for more information.

**ATC CODE:**
DOCEtaxel - L01CD02

**REFERENCES:**

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NCCP Chemotherapy Regimen

**NCCP Regimen:**

**DOCTaxel**

Monotherapy

75mg/m$^2$ – 21 day cycle

Published: 10/02/2014

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Version number: 4

Tumour Group: Gastrointestinal/Genitourinary/Lung/Breast/gynaecology

NCCP Regimen Code: 00203

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00203

**ISM0 Contributor:** Prof Maccon Keane

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**Comments and feedback welcome at oncologydrugs@cancercontrol.ie.**

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1 This is an unlicensed indication for the use of DOCTaxel in Ireland. Patient’s should be informed of this and consented to treatment in line with the hospital’s policy on the use of unlicensed medication and unlicensed or “off label” indications. Prescribers should be fully aware of their responsibility in communicating any relevant information to the patient and also ensuring that the unlicensed or “off label” indication has been acknowledged by the hospital’s Drugs and Therapeutics Committee, or equivalent, in line with hospital policy.

2 ODMS – Oncology Drug Management System

CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes