**Docetaxel Monotherapy 75mg/m² – 21 day cycle**

**INDICATIONS FOR USE:**

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>*Reimbursement Indicator</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></td>
</tr>
<tr>
<td>In combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer</td>
<td>C61</td>
<td>00203b</td>
<td></td>
</tr>
</tbody>
</table>

*If a reimbursement indicator (e.g. ODMS, CDS) is not defined, the drug and its detailed indication have not gone through the formal reimbursement process as legislated for in the Health (Pricing and Supply of Medical Goods) Act 2013.*

**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.

**Prostate carcinoma:** Treatment 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 or 5% glucose 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

**Prostate Cancer:** Prednisone or prednisolone 5 mg orally twice daily or 10mg once daily is administered continuously from day 1-21.

**ELIGIBILITY:**

- Indications as above
- ECOG 0-2

**EXCLUSIONS:**

- Hypersensitivity to docetaxel or to any of the excipients
- Severe liver impairment
- Baseline neutrophil count < 1.5 x 10⁹ cells/L

**PRESCRIPTIVE AUTHORITY:**

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

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TESTS:
- Baseline tests:
  - FBC, U&Es, LFTs
- Regular tests:
  - FBC, U&Es, LFTs*
  - *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>
</tbody>
</table>
| Febrile neutropenia or <0.5 for more than 1 week | Reduce dose from 75 to 60mg/m². Discontinue treatment if continues at lower dose.

Renal and Hepatic Impairment:
No data available in patients with severely impaired renal function

Table 2: Dose modification of docetaxel in hepatic impairment.

<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</td>
<td>and</td>
<td>&gt; 1.5 ULN</td>
<td>75 mg/m²</td>
</tr>
<tr>
<td>&gt; 6 ULN</td>
<td>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>
</tr>
</tbody>
</table>

Management of adverse events:
Table 3: Dose modification schedule based on 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>

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SUPPORTIVE CARE:
EMETOGENIC POTENTIAL: Low (Refer to local policy).

PREMEDICATIONS:

- **Non-small cell lung cancers**: 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.
- **Prostate cancer**: Premedicate with oral dexamethasone 8 mg, 12 hours, 3 hours and 1 hour before the docetaxel infusion.
- **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.
- **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.
NCCP Chemotherapy Regimen

- Current drug interaction databases should be consulted for more information.

**ATC CODE:**
Docetaxel - L01CD02

**REFERENCES:**

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Approved By</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10/02/2014</td>
<td></td>
<td>Dr Maccon Keane</td>
</tr>
<tr>
<td>2</td>
<td>30/05/2015</td>
<td>Modification of premedication regimen</td>
<td>Dr Maccon Keane</td>
</tr>
<tr>
<td>3</td>
<td>23/05/2019</td>
<td>Updated with new NCCP regimen format</td>
<td>Prof Maccon Keane</td>
</tr>
</tbody>
</table>

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

1 ODMS – Oncology Drug Management System
CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes
Further details on the Cancer Drug Management Programme is available at; http://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/cdmp/

<table>
<thead>
<tr>
<th>NCCP Regimen: Docetaxel Monotherapy 75mg/m² – 21 day cycle</th>
<th>Published: 10/02/2014</th>
<th>Version number: 3</th>
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<tbody>
<tr>
<td>Tumour Group: Genitourinary and Lung</td>
<td>ISMO Contributor: Prof Maccon Keane</td>
<td>Page 4 of 4</td>
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<tr>
<td>NCCP Regimen Code: 00203</td>
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