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Docetaxel Monotherapy 50mg/m$^2$ – 14 day cycle

INDICATIONS FOR USE:

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Protocol Code</th>
</tr>
</thead>
<tbody>
<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>00313a</td>
</tr>
</tbody>
</table>

ELIGIBILTY:

- Indications as above
- ECOG status 0-2
- Life expectancy > 3 months

EXCLUSIONS:

- Hypersensitivity to docetaxel or to any of the excipients
- Severe liver impairment
- Baseline neutrophil count < 1,500 cells/mm$^3$

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

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 patients individual clinical circumstances.

Prostate carcinoma: Treatment administered every 14 days until disease progression or unacceptable toxicity develops.
NCCP Chemotherapy Protocol

Docetaxel Monotherapy

**Day 1**
- **Drug**: Docetaxel
- **Dose**: 50mg/m²
- **Route**: IV infusion
- **Diluent & Rate**: *250ml 0.9% sodium chloride or 5% glucose over 60min
- **Cycle**: Repeat every 14 days

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

**Prostate Cancer**: Prednisone or prednisolone 5 mg orally twice daily or 10mg once daily is administered continuously from day 1-14.

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

**Haematological:**

<table>
<thead>
<tr>
<th>ANC (x10⁹/L)</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1.5</td>
<td>50mg/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 50 to 40mg/m². Discontinue treatment if continues at lower dose.</td>
</tr>
</tbody>
</table>

**Hepatic Dysfunction:**

<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/or &gt; 1.5 ULN</td>
<td>&gt; 3.5 ULN (AST and ALT)</td>
<td>&gt; ULN</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Table 1**: 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 40mg/m²</td>
</tr>
<tr>
<td>Grade &gt;2 peripheral neuropathy</td>
<td>If the patient continues to experience these reactions at 40 mg/m², the treatment should be discontinued</td>
</tr>
<tr>
<td>Grade 3 or 4 stomatitis</td>
<td></td>
</tr>
</tbody>
</table>

NCCP Protocol: Docetaxel Monotherapy 50mg/m²
- 14 day cycle

Published: 03/05/2016
Review: 03/05/2018
Version number: 1

Tumour Group: Genitourinary
NCCP Protocol Code: 00313

ISMO Contributor: Dr Maccon Keane

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SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Low (Refer to local policy).

PREMEDICATIONS:
- 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 (1,2)

TAKE HOME MEDICATIONS:
Prednisolone tablets

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 > 1500 cells/mm³

- **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

**REIMBURSEMENT CATEGORY**:  
Docetaxel is funded through local hospital budgets (Feb. 2016).

**PRESCRIPTIVE AUTHORITY**:  
Medical Oncologist

**REFERENCES**:  


<table>
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<td>1</td>
<td>3/05/2016</td>
<td>Initial Draft</td>
<td>Dr Maccon Keane</td>
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Comments and feedback welcome at oncologydrugs@cancercontrol.ie.