

DOCEtaxel Monotherapy 50mg/m² – 14 day cycle

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
In combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer	C61	00313a	Hospital

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.

DOCEtaxel is administered once every 14 days until disease progression or unacceptable toxicity develops.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	DOCEtaxel	50mg/m ²	IV infusion	*250ml 0.9% sodium chloride over 60min	Repeat every 14 days
*75-185 mg 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					

ELIGIBILITY:

- Indications as above
- ECOG 0-2

EXCLUSIONS:

- Hypersensitivity to DOCEtaxel or to any of the excipients
- Severe liver impairment
- Baseline neutrophil count < 1.5x10⁹ 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

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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: Recommended dose modification of DOCetaxel for haematological toxicity

ANC (x10 ⁹ /L)	Dose
≥ 1.5	50mg/m ²
0.5 to less than 1.5	Delay treatment until recovery
Febrile neutropenia or <0.5 for more than 1 week	Reduce dose from 50 mg/m ² to 40mg/m ² . Discontinue treatment if continues at lower dose.

Renal and Hepatic Impairment:

Table 2. Recommended dose modification of DOCetaxel in renal and hepatic impairment

Renal impairment	Hepatic impairment					Dose
	Serum Bilirubin		AST and/or ALT		Alkaline Phosphatase	
No data available in patients with severely impaired renal function			> 1.5 ULN	and	> 2.5 ULN	100%
	> ULN	and/or	> 3.5 ULN (AST and ALT)	and	> 6 ULN	Stop treatment unless strictly indicated and should be discussed with a Consultant.

Management of adverse events:

Table 3: Recommended dose modification schedule based on adverse events

Adverse reactions	Dose
Grade 3 skin reaction	Decrease dose to 40mg/m ² If the patient continues to experience these reactions at 40 mg/m ² , the treatment should be discontinued
Grade >2 peripheral neuropathy	
Grade 3 or 4 stomatitis	

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 (5, 6).

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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.

- **Neutropenia:** Most frequent adverse reaction. Fever or other evidence of infection must be assessed promptly and treated appropriately. Frequent blood count monitoring should be conducted in all patients treated with DOCEtaxel. DOCEtaxel should be administered when the neutrophil count is $> 1.5 \times 10^9$ cells/L
- **Neutropenic Enterocolitis:** A number of cases of neutropenic enterocolitis have been reported in patients treated with DOCEtaxel in France (7). This is a known and rare side effect of DOCEtaxel which may affect up to one in 1,000 people.
- **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).
- **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

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2. Picus J, Schultz M, Cochrane J. A phase II trial of docetaxel in patients with hormone refractory prostate cancer. Long term results. *Proc Am SocClinOncol*, 1999;18a (abstract1206).
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Version	Date	Amendment	Approved By
1	03/05/2016		Dr Maccon Keane
2	03/05/2018	Updated with new NCCP regimen template, standardisation of treatment table, updated re neutropenic enterocolitis	Prof Maccon Keane
3	12/05/2020	Regimen review Updated recommended dose modification of DOCEtaxel in renal and hepatic impairment table	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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