

Docetaxel & Prednisolone

Indication

Castrate resistant metastatic prostate cancer

Hormone naïve metastatic prostate cancer in combination with androgen deprivation therapy (ADT)

Regimen details

Docetaxel 75mg/m² IV in 250ml 0.9% sodium chloride over 1 hour

Prednisolone 10mg orally daily

Cycle frequency

Every 21 days

Number of cycles

Castrate resistant: maximum 10 cycles

Hormone naïve: maximum 6 cycles

Administration

Monitor patient for hypersensitivity reactions, especially during the first two infusions

Pre-medication

Dexamethasone 8mg orally twice daily for 3 days starting 24 hours before chemotherapy

Emetogenicity

Low

Additional supportive medication

None

Extravasation

Irritant

Investigations – pre first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days
Calcium	14 days
PSA	14 days

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT (including AST), PSA, LDH

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	Limit
Neutrophil count	$\geq 1.5 \times 10^9/L$
Platelet count	$\geq 100 \times 10^9/L$
Bilirubin	\leq ULN
AST	$< 1.5 \times$ ULN
Alkaline phosphatase	$< 2.5 \times$ ULN (unless due to bone mets only)

Dose modifications

Consider 25% dose reduction:

- Febrile neutropenia
- Severe/prolonged neutropenia/thrombocytopenia
- Grade 3 diarrhoea
- Grade 2 neuropathy
- Rising ALT/AST

Discontinue treatment:

- Life threatening sepsis
- Grade 4 toxicity

Renal impairment:

No modifications required

Hepatic impairment:

AST/ALT (x ULN)		Alkaline phosphatase* (x ULN)	Docetaxel dose
≤ 1.5	And	< 2.5	100%
> 1.5	Or	$\geq 2.5-6$	75%
> 3.5	Or	≥ 6	Discuss with consultant

*unless due to bone metastases only

If bilirubin $>$ ULN, withhold dose (or discuss with consultant)

Adverse effects –

for full details consult product literature/ reference texts

- **Serious side effects**

Secondary malignancy
Myelosuppression
Infusion related reactions
Anaphylaxis
Interstitial pneumonitis
Teratogenicity
Infertility
Cardiotoxicity

- **Frequently occurring side effects**

Diarrhoea
Constipation
Fatigue
Nausea and vomiting
Myelosuppression
Stomatitis and mucositis
Peripheral neuropathy
Arthralgia and myalgia

- **Other side effects**

Alopecia
Fluid retention
Deranged liver function
Phlebitis
Skin toxicity
Nail changes

Significant drug interactions

– for full details consult product literature/ reference texts

Use with caution with strong inhibitors (e.g. ciclosporin, ketoconazole or erythromycin) or inducers (e.g. rifampicin) of CYP3A4 as these may affect docetaxel metabolism

Additional comments

Docetaxel contains ethanol, equivalent to approximately 40ml of wine per dose

References

Docetaxel SPC - <https://www.medicines.org.uk/emc/product/5762/smpc>

South West Clinical Network Cancer Protocols - <http://www.swscn.org.uk/guidance-protocols/cancer-protocols/>

THIS PROTOCOL HAS BEEN DIRECTED BY DR BIRTLE, DESIGNATED LEAD CLINICIAN FOR PROSTATE CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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