

## Chemotherapy Protocol

### BREAST CANCER

#### DOCETAXEL (75)

#### Regimen

- Breast Cancer – Docetaxel (75)

#### Indication

- Treatment of locally advanced or metastatic HER2 positive breast cancer that has failed to adequately respond to an anthracycline containing therapy or when further anthracycline therapy is contra-indicated
- WHO Performance status 0, 1, 2

#### Toxicity

Drug	Adverse Effect
Docetaxel	Hypersensitivity, fluid retention, neuropathy, joint pains, nail changes, fatigue

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

#### Monitoring

#### *Regimen*

- FBC, U&E's and LFT's prior to each cycle

#### Dose Modifications

The dose modifications listed are for haematological, liver and renal function only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.

Please discuss all dose reductions / delays with the relevant consultant before prescribing if appropriate. The approach may be different depending on the clinical circumstances. The following is a general guide only.

#### *Haematological*

Prior to prescribing cycle one the following treatment criteria must be met;

Criteria	Eligible Level
Neutrophil	equal to or more than $1.5 \times 10^9/L$ (unless due to bone marrow impairment)
Platelets	equal to or more than $100 \times 10^9/L$ (unless due to bone marrow impairment)

Consider blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL

Toxicity	Grade (NCI-CTC)	75mg/m <sup>2</sup>	60mg/m <sup>2</sup>
Neutrophil	1	75mg/m <sup>2</sup>	60mg/m <sup>2</sup>
	2	Delay until grade 1 then 75mg/m <sup>2</sup>	Delay until grade 1 then 60mg/m <sup>2</sup>
	3	Delay until grade 1 then 75mg/m <sup>2</sup>	Delay until grade 1 then 60mg/m <sup>2</sup>
	4	Delay until grade 1 then 60mg/m <sup>2</sup>	Stop
Febrile Neutropenia	3	Delay until grade 1 then 60mg/m <sup>2</sup>	Stop
	4	Delay until grade 1 then 60mg/m <sup>2</sup>	Stop
Platelets	Greater than or equal to $100 \times 10^9/L$	75mg/m <sup>2</sup>	60mg/m <sup>2</sup>
	Less than $100 \times 10^9/L$	Delay until greater than or equal to $100 \times 10^9/L$ then 60mg/m <sup>2</sup>	Stop

### Kidney Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Docetaxel	N/A	No dose adjustment needed

### Liver Impairment

Drug	Bilirubin (µmol/L)		AST/ALT (units)		Alk Phos (units)	Dose (% of original dose)
Docetaxel	N/A		1.5xULN or greater	and	2.5xULN or greater	Give 75%
	Greater than ULN	and/or	3.5xULN or greater	and	6xULN or greater	Not Recommended

### Other

Dose reductions or interruptions in therapy are not necessary for those toxicities that are considered unlikely to be serious or life threatening. For example, alopecia, altered taste or nail changes.

Peripheral neuropathy at NCI-CTC grade 3 should result in a dose reduction from 75mg/m<sup>2</sup> to 60mg/m<sup>2</sup> once the neuropathy has resolved to NCI-CTC grade 2 or below. If the NCI-CTC grade 3 neuropathy occurred at doses lower than 75mg/m<sup>2</sup> or a NCI-CTC grade 4 toxicity develops consider stopping treatment.

Excessive tearing / lacrimation are related to cumulative docetaxel doses and occur after a median of 400mg/m<sup>2</sup>. Symptomatic treatment with hypromellose 0.3% eye drops four times a day may help. However, if the ocular irritation continues reduce the docetaxel dose to 80% of the original dose in the first instance.

Delay the docetaxel where a NCI-CTC grade 3 cutaneous toxicity is present on day one of the cycle until it resolves to NCI-CTC grade 1 or below. The subsequent doses of docetaxel should be reduced from 75mg/m<sup>2</sup> to 60mg/m<sup>2</sup>. If it occurs with a dose of 60mg/m<sup>2</sup> or if there is no recovery after two weeks, docetaxel treatment should be stopped. Where a NCI-CTC grade 3 cutaneous toxicity occurs between cycles with recovery by day one then reduce the docetaxel dose as described. Docetaxel should be stopped in response to a NCI-CTC grade 4 cutaneous toxicity.

### [Regimen](#)

Docetaxel is highly myelosuppressive and in those with poor bone marrow reserves (for example due to extensive prior treatment, bone metastasis or extensive skeletal radiation) consider a starting dose of 55mg/m<sup>2</sup> with a view to increase to 75mg/m<sup>2</sup> if well tolerated.

### **21 day cycle for 6 cycles**

Drug	Dose	Days	Administration
Docetaxel	75mg/m <sup>2</sup>	1	Intravenous infusion in 250ml sodium chloride 0.9% over 60 minutes

### [Dose Information](#)

- Docetaxel will be dose banded as per the CSCCN agreed bands
- Docetaxel induced fluid retention can lead to weight gain. This is not a reason to alter the doses

### [Administration Information](#)

Hypersensitivity reactions tend to occur with the first or second infusion of docetaxel. The docetaxel infusion should not be interrupted for minor symptoms such as flushing or localised rashes. Immediately discontinue the infusion for severe reactions which include profound hypotension, bronchospasm and generalised erythema.

- Docetaxel doses of more than 200mg should be diluted in 500ml sodium chloride 0.9% (maximum concentration 0.74mg/ml)

### [Extravasation](#)

- Docetaxel – exfoliant

### Additional Therapy

- Antiemetics

15-30 minutes before chemotherapy

- metoclopramide 10mg oral or intravenous

As take home medication

- metoclopramide 10mg three times a day when required oral

- To prevent fluid retention and hypersensitivity reactions prescribe dexamethasone 8mg twice a day orally for three days starting 24 hours before the docetaxel administration. On the occasions where individuals attend for treatment and have forgotten to take the dexamethasone pre-medication administer dexamethasone 20mg, or nearest equivalent dose, once only intravenous bolus.
- Gastric protection with a proton pump inhibitor or a H<sub>2</sub> antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

### Coding

- Procurement – X71.1
- Delivery – X72.3

### References

1. NICE (2009). Clinical Guideline CG81. Advanced breast cancer: Diagnosis and Treatment. DOH:London.

## REGIMEN SUMMARY

### Docetaxel (75)

#### Cycle 1, 2, 3, 4, 5

##### Day Minus One

1. Dexamethasone 8mg twice a day oral\*

##### Day One

2. Dexamethasone 8mg twice a day oral (from TTO)\*
3. Metoclopramide 10mg oral or intravenous
4. Docetaxel 75mg/m<sup>2</sup> intravenous infusion in 250ml sodium chloride 0.9% over 60 minutes

##### Take Home Medicines

5. Dexamethasone 8mg twice a day oral for 3 days starting the day before the docetaxel infusion
6. Metoclopramide 10mg three times a day when required oral

#### Cycle 6

##### Day Minus One

1. Dexamethasone 8mg twice a day oral\*

##### Day One

2. Dexamethasone 8mg twice a day oral (from TTO)\*
3. Metoclopramide 10mg oral or intravenous
4. Docetaxel 75mg/m<sup>2</sup> intravenous infusion in 250ml sodium chloride 0.9% over 60 minutes

##### Take Home Medicines

5. Metoclopramide 10mg three times a day when required oral
6. Dexamethasone 8mg twice a day oral for the day after chemotherapy\*

\* In Aria Planner the dexamethasone 8mg twice daily will appear on days 1, 2, 3 of treatment. This is the supply for the next cycle. The administration instructions reflect this. On the last cycle no dexamethasone will appear for prescribing.

## DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	August 2014	Header changed Toxicities removed Adverse effects tabulated ≥ removed and written in full Dose modification tabulated Regimen tabulated Nearest equivalent dose added to dexamethasone premedication Metoclopramide dose changed to 10mg Bolus removed from intravenous bolus throughout text OPCS code updated Disclaimer added	Donna Kimber Pharmacy Technician	Dr Debbie Wright Pharmacist
1	Dec 2011	None	Anna Bunch Pharmacist  Dr Debbie Wright Pharmacist	Dr Ellen Copson Consultant Medical Oncologist  Dr Caroline Archer Consultant Medical Oncologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust  
NHS Isle of Wight  
Portsmouth Hospitals NHS Trust  
Salisbury Hospital NHS Foundation Trust  
University Hospital Southampton NHS Foundation Trust  
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.