Chemotherapy Protocol

BREAST CANCER

DOCETAXEL (100)

Regimen

- Breast Cancer – Docetaxel (100)

Indication

- Neoadjuvant / adjuvant treatment of breast cancer
- 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 $1x1.5^{9}$/L (unless due to bone marrow impairment)
Platelets	equal to or more than $100x10^{9}$/L (unless due to bone marrow impairment)

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

		Previous Docetaxel Dose		
Toxicity	**Grade (NCI-CTC)**	**100mg/m^2**	**75mg/m^2**	**60mg/m^2**
Neutrophil	1	100mg/m^2	75mg/m^2	60mg/m^2
	2	Delay until grade 1 then 100mg/m^2	Delay until grade 1 then 75mg/m^2	Delay until grade 1 then 60mg/m^2
	3	Delay until grade 1 then 100mg/m^2	Delay until grade 1 then 75mg/m^2	Delay until grade 1 then 60mg/m^2
	4	Delay until grade 1 then 75mg/m^2	Delay until grade 1 then 60mg/m^2	Stop
Febrile Neutropenia	3	Delay until grade 1 then 75mg/m^2	Delay until grade 1 then 60mg/m^2	Stop
	4	Delay until grade 1 then 75mg/m^2	Delay until grade 1 then 60mg/m^2	Stop
Platelets	Greater than or equal to 100x10^9/L	100mg/m^2	75mg/m^2	60mg/m^2
	Less than 100x10^9/L	Delay until greater than or equal to 100x10^9/L the 75mg/m^2	Delay until greater than or equal to 100x10^9/L the 60mg/m^2	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 100mg/m^2 to 75mg/m^2 or from 75mg/m^2 to 60mg/m^2 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^2 or a NCI-CTC grade 4 toxicity develops stop treatment.

Excessive tearing / lacrimation are related to cumulative docetaxel doses and occur after a median of 400mg/m². 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 to from 100mg/m^2 to 75mg/m^2 or from 75mg/m^2 to 60mg/m^2. If it occurs with a dose of 60mg/m^2 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 75mg/m² with a view to increase to 100mg/m² if well tolerated.

21 day cycle for 6 cycles

Drug	Dose	Days	Administration
Docetaxel	100mg/m^2	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.

- Growth factor according to local formulary choice. For example;

  - filgrastim or bioequivalent 300microgram once a day subcutaneous for seven days starting on day three of the cycle
  - lenograstim or bioequivalent 263microgram once a day subcutaneous for seven days starting on day three of the cycle
  - pegfilgrastim or bioequivalent 6mg once a day subcutaneous on day two

- Gastric protection with a proton pump inhibitor or a H_2 antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

Coding

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

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

REGIMEN SUMMARY

Docetaxel (100)

Cycles 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 100mg/m² 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

7. Growth factor according to local formulary choice. For example;

- filgrastim or bioequivalent 300microgram once a day subcutaneous for seven days starting on day three of the cycle
- lenograstim or bioequivalent 263microgram once a day subcutaneous for seven days starting on day three of the cycle
- pegfilgrastim or bioequivalent 6mg once a day subcutaneous on day two of the cycle

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 100mg/m² intravenous infusion in 250ml sodium chloride 0.9% over 60 minutes

Take Home Medicines

5. Dexamethasone 8mg twice a day oral for the day after chemotherapy*

6. Metoclopramide 10mg three times a day when required oral

7.Growth factor according to local formulary choice. For example;

- filgrastim or bioequivalent 300microgram once a day subcutaneous for seven days starting on day three of the cycle
- lenograstim or bioequivalent 263microgram once a day subcutaneous for seven days starting on day three of the cycle
- pegfilgrastim or bioequivalent 6mg once a day subcutaneous on day two of the cycle

* 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. No supply will be made on cycle 6.

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 dose added to dexamethasone premedication Metoclopramide dose changed to 10mg Bolus removed from intravenous bolus throughout text 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.