Chemotherapy Protocol

BLADDER

GEMCITABINE (21 day)

Regimen

- Bladder-Gemcitabine

Indication

- Locally advanced or metastatic urothelial cancer in patients unsuitable for cisplatin or carboplatin.
- WHO performance status 0,1,2
- Palliative intent

Toxicity

Drug	Adverse Effect
Gemcitabine	Peripheral oedema, diarrhoea, constipation, rash, respiratory problems, influenza like symptoms, radiosensitising

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

Monitoring

- FBC, LFTs and U&Es prior to day 1 and 8 of each cycle

Dose Modifications

The dose modifications listed are for haematological, liver and renal function and drug specific toxicities 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.

Haematological

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

Day 1

Neutrophils ($x10^9$/L)	Dose Modifications
1 or greater	100%
less than 1	1st Occurrence Delay until recovery 2nd Occurrence Delay until recovery then give 75% of the original dose
Febrile Neutropenia	1st Occurrence Delay until recovery and then re-start treatment using 75% of the original dose
Platelets ($x10^9$/L)	**Dose Modifications**
100 or greater	100%
less than 100	1st Occurrence Delay until recovery then give 75% of the original dose 2nd Occurrence Delay until recovery then give 50% of the original dose

Day 8

Neutrophils ($x10^9$/L)	Dose Modifications
1 or greater	100%
0.5 - 1	75%
less than 0.5	Omit
Platelets ($x10^9$/L)	**Dose Modifications**
100 or greater	100%
50 -100	75%
Less than 50	Omit

If dose modifications to the gemcitabine dose are required on day 1 then continue with the reduced dose on day 8.

Hepatic Impairment

Drug	Bilirubin (µmol/L)	AST/ALT (units/L)	Dose (% of original dose)
Gemcitabine	30 or greater*	N/A	Initiate treatment at 800mg/m^2

*Limit reflects local practice and may vary from published sources

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Gemcitabine	less than 30ml/min	Consider dose reduction

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.

For all other non-haematological NCI-CTC grade 3 and above toxicities delay treatment until the adverse effect has resolved to NCI-CTC grade 1 or below. The dose of the causative agent should then be reduced to 75% of the original dose or discontinued as appropriate.

Regimen

21 day cycle for 6 cycles

Drug	Dose	Days	Administration
Gemcitabine	1000mg/m^2	1 and 8	Intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

Dose Information

- Gemcitabine will be dose banded as per the CSCCN agreed dose bands

Administration Information

Extravasation

- Gemcitabine – neutral

Additional Therapy

- Antiemetics

  15 - 30 minutes prior to chemotherapy

  - metoclopramide 10mg oral or intravenous

As take home medication

- metoclopramide 10mg oral three times a day as required

- Mouthwashes according to local or national policy on the treatment of mucositis
- 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 (OPCS 4.6)

- Procurement – X70.4
- Delivery – X 72.3 & X72.4

References

1. Gebbia V, Testa A, Borsellino N et al. Single agent 2, 2-difluorodeoxycytidine in the treatment of metastatic urothelial carcinoma: a phase II study. Clin Ter 1999; 150 (1): 11-15.
2. Castagneto B, Zai S, Marenco D et al. Single-agent gemcitabine in previously untreated elderly patients with advanced bladder carcinoma: response to treatment and correlation with the comprehensive geriatric assessment. Oncology 2004:67(1):27-32

REGIMEN SUMMARY

Gemcitabine (21 day)

Day 1

1. Metoclopramide 10mg oral or intravenous

2. Gemcitabine 1000mg/m^2 intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

Take Home Medicines

3. Metoclopramide 10mg oral three times a day when required for nausea
   Administration Instructions
   Please supply 10 days or an original pack if appropriate to cover day 1 and 8

Day 8

4. Metoclopramide 10mg oral or intravenous

5. Gemcitabine 1000mg/m^2 intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.1	May 2015	"(21 day)" added to title and footer Header changed Statement re local bilirubin limit added Metoclopramide dose changed to 10mg Bolus removed from intravenous bolus throughout text Mucositis recommendation changed OPCS code updated Day 8 details added to regimen summary Metoclopramide administration instructions updated Disclaimer added	Donna Kimber Pharmacy Technician	Rebecca Wills Pharmacist
1	Dec 2012	None	Rebecca Wills Pharmacist Dr Deborah Wright Pharmacist	Dr Joanna Gale Consultant Medical Oncologist Dr Mathew Wheater 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 Hospitals 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.