Chemotherapy Protocol

LUNG CANCER – NON-SMALL CELL (NSCLC)

GEMCITABINE

Regimen

- NSCLC - Gemcitabine

Indication

- Second line therapy of stage III or IV NSCLC
- WHO Performance status 0, 1, 2
- Palliative intent

Toxicity

Drug	Adverse Effects
Gemcitabine	Peripheral oedema, diarrhoea, constipation, rash, respiratory problems (pneumonitis), influenza like symptoms, radiosensitising, transient elevation of LFTs

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

Monitoring

Disease

- A baseline chest x-ray should be performed before starting treatment and up to date (ideally within 1 month) cross section imaging should also be performed

Regimen

- FBC, LFTs and U&Es prior to each cycle and FBC day 8
- A chest x-ray should be performed before 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.

Haematology

Prior to prescribing on day one of cycle one the following criteria must be met;

Criteria	Eligible Level
Neutrophil	equal to or more than $1.5x10^9$/L
Platelets	equal to or more than $100x10^9$/L

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

Subsequently on day 1 if the neutrophils are less than 1.5 $x10^9$/L then in the first instance delay treatment for 7 days. If counts recover at this point continue at the initial dose. If counts remain low continue with treatment using a 20% dose reduction. If the myelosuppression recurs despite this dose reduction stop treatment.

If the platelets are less than $100x10^9$/L then in the first instance delay treatment for 7 days. If the counts recover at this point continue at the initial dose. If the counts still fall within this range continue using a 20% dose reduction. If the platelet level falls below $50x10^9$ /L reduce the dose by 50%

Dose adjustments for day eight should be made according to local practice guidelines or procedures.

Drug	Bilirubin µmol/L		AST/ALT units	Dose (%of original dose)
Gemcitabine	AST elevations do not seem to cause dose limiting toxicities. If bilirubin is greater than 27µmol/L, initiate treatment with dose of 800 mg/m^2.			

Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Gemcitabine	Consider dose adjustments if the CrCl is less than 30ml/min	

Regimen

21 day cycle for 4 cycles

Drug	Dose	Days	Administration
Gemcitabine	1250mg/m^2	1, 8	Intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

Dose Information

- Gemcitabine will be dose banded as per the CSCCN agreed 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 three times a day when required

- 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 – X70.4
- Delivery – X72.3, X72.4

References
1.National Institute of Clinical Excellence (2005). CG24. The Diagnosis and Treatment of Lung Cancer. Methods, Evidence and Guidance. DOH: London.
2.Sederholm C. Gemcitabine versus gemcitabine / carboplatin in advanced non-small cell lung cancer: preliminary findings in a phase III trial of the Swedish Lung Cancer Study Group. Semin Oncol 2002; 29 (3 suppl 9); 50-54.

REGIMEN SUMMARY

Gemcitabine

Day One

1. Metoclopramide 10mg oral or intravenous

2. Gemcitabine 1250mg/m^2 intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

Take Home Medicines

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

Day Eight

4. Metoclopramide 10mg oral or intravenous

5. Gemcitabine 1250mg/m^2 intravenous infusion in 250ml sodium chloride 0.9% over 30 minutes

DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1.2	December 2013	CSCCN removed from header Toxicities removed Tables used throughout < and > removed and replaced with words Gemcitabine hepatic impairment updated Metoclopramide dose changed to 10mg Antiemetic routes written in full and stat removed. Bolus removed from injection OPCS updated Summary re-numbered Document control tabulated Hospitals and disclaimer added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician
1.1	Sept 2010	Font changed to Arial Header altered to include "Strength through Partnership" Drug names given capitals in regimen Extravasation moved to under Administration Information Footer changed to include regimen name and review date removed Standard paragraph added to introduction in dose modifications Dose modifications format (not information) changed Coding added Summary page added Document control added	Dr Deborah Wright Pharmacist	Donna Kimber Pharmacy Technician

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 NHS Foundation Trust
University Hospital Southampton NHS Foundation Trust
Western Sussex Hospitals NHS 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.