Gemcitabine (NSCLC)

Indication
First line palliative therapy for patients with NSCLC who cannot receive platinum-based combination therapy.

ICD-10 codes
Codes pre-fixed with C34

Regimen details

Day	Drug	Dose	Route
1 and 8	Gemcitabine	1250 mg/m²	IV infusion

Cycle frequency
21 days

Number of cycles
4 cycles

Administration
Gemcitabine is administered in 250-500mL sodium chloride 0.9% over 30 minutes.

Pre-medication
Antiemetics as per local guidelines.

Emetogenicity
This regimen has low emetic potential.

Additional supportive medication
Nil

Extravasation
Gemcitabine – neutral (Group 1)

Investigations – pre first cycle

Investigation	**Validity period** (or as per local practice)
FBC	14 days
U+E (including creatinine)	14 days
LFTs	14 days

Investigations - pre subsequent cycles

Investigation	**Validity period** (or as per local practice)
FBC	96 hours
U+E (including creatinine)	7 days
LFTs	7 days

In addition FBC is required on day 8 prior to gemcitabine

Standard limits for administration to go ahead

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

Investigation	Limit
Neutrophils	≥1.0 x 10^9/L
Platelets	≥100 x 10^9/L
Creatinine Clearance (CrCl)	≥30 mL/min
Bilirubin	< 1.5 x ULN

Dose modifications

- **Haematological toxicity**

Day	Neutrophils (x 10^9/L)		Platelets (x 10^9/L)	Dose adjustment
Day 1	≥ 1.0	and	≥ 100	100%
	< 1.0	or	< 100	Delay 1 week
Day 8	≥ 1.0	and	> 100	100%
	0.5 – 1.0	or	50-100	75%
	<0.5	or	< 50	Omit

Dose reductions are for the day of treatment only and can be returned to full dose after count recovery.
If after 1 week delay the bloods have not recovered, delay treatment again until recovery and continue with a dose reduction for future cycles.

If febrile neutropenia reduce gemcitabine dose to 75%.

- **Renal impairment**

CrCl (mL/min)	**Gemcitabine dose**
≥ 30	100%
< 30	Consider dose reduction

- **Hepatic impairment**

There is limited information about use of gemcitabine in hepatic impairment, therefore use with caution. AST elevations do not appear to cause dose limiting toxicity.
If bilirubin > 1.5 x ULN consider reducing gemcitabine dose to 800 mg/m2.

- **Other toxicities**

Toxicity	Definition	Gemcitabine dose
Diarrhoea	Grade 1	100%
	Grade 2	Omit until ≤ grade 1 then restart at 100% dose
	Grade 3	Omit until ≤ grade 1 then 75% dose
	Grade 4	Omit until ≤ grade 1 then 50% dose
Stomatitis	Grade 1	100%
	Grade 2	Omit until ≤ grade 1 then restart at 100% dose
	Grade 3	Omit until ≤ grade 1 then 75% dose
	Grade 4	Omit until ≤ grade 1 then 50% dose

Adverse effects - for full details consult product literature/ reference texts

- **Serious side effects**

Interstitial pneumonitis, ARDS
Cardiotoxicity
Hepatotoxicity

- **Frequently occurring side effects**

Nausea and vomiting
Myelosuppression
Dyspnoea
Mucositis, stomatitis
Diarrhoea, constipation
Oedema
Proteinuria
Haematuria
Flu-like symptoms

- **Other side effects**

Raised transaminases
Alopecia (mild)
Headache
Fatigue

Significant drug interactions – for full details consult product literature/ reference texts

Warfarin/coumarin anticoagulants: increased or fluctuating anticoagulant effects. Avoid if possible, consider switching patient to a low molecular weight heparin during treatment or if the patient continues taking an oral anticoagulant monitor the INR at least once a week and adjust dose accordingly.

Additional comments

Nil

References

- National Institute of Health and Clinical Excellence Guideline CG121. Lung Cancer. The diagnosis and treatment of lung cancer Accessed 21 May 2014 via www.nice.org.uk
- Summary of Product Characteristics Gemcitabine (Lilly) accessed 21 May 2014 via www.medicines.org.uk
- Allwood M, Stanley A, Wright P, editors. The cytotoxics handbook. 4th ed. Radcliffe Medical Press. 2002.

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