

## Gemcitabine (pancreas)

### Indication

First-line palliative therapy for locally advanced, metastatic or relapsed pancreatic cancer.

### ICD-10 codes

Codes pre-fixed with C25

### Regimen details

Cycle	Day	Drug	Dose	Route
1	1, 8, 15, 22, 29, 36, 43	Gemcitabine	1000 mg/m <sup>2</sup>	IV infusion
2-5	1, 8, 15	Gemcitabine	1000 mg/m <sup>2</sup>	IV infusion

### Cycle frequency

Weekly for 19 weeks except for weeks 8, 12, 16 and 19 (i.e. one 8-week cycle of 7 weeks on, 1 week off, followed by four 4-week cycles of 3 weeks on and 1 week off).

### Number of cycles

As above

### Administration

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

### Pre-medication

None

### Emetogenicity

This regimen has moderate-low emetic potential.

### Additional supportive medication

None

### Extravasation

Gemcitabine – neutral (Group 1)

### Investigations – pre first cycle

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

### Investigations – pre subsequent cycles

Investigation	Validity period (or as per local policy)
FBC	96 hours (pre day 1) 24 hours (pre all other treatment days)
U+E (including creatinine)	7 days (days 1 and 22 of cycle 1, day 1 cycles 2-5)
LFTs	7 days (days 1 and 22 of cycle 1, day 1 cycles 2-5)

## 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	$\geq 1.0 \times 10^9/L$
Platelets	$\geq 100 \times 10^9/L$
Bilirubin	$\leq 1.5 \times \text{ULN}$
Creatinine Clearance (CrCl)	$\geq 30 \text{ mL/min}$

## Dose modifications

### • Haematological toxicity

Neutrophils ( $\times 10^9/L$ )		Platelets ( $\times 10^9/L$ )	Gemcitabine dose
$\geq 1.0$	and	$> 100$	100%
0.5 – 1.0	or	50-100	75%
$< 0.5$	or	$< 50$	omit

If febrile neutropenia (neutrophils  $< 0.5 \times 10^9/L$  and fever requiring IV antibiotics) – reduce gemcitabine dose to 75%.

### • Renal impairment

If CrCl  $< 30 \text{ mL/min}$  consider dose reduction (consultant decision).

### • Hepatic impairment

Lack of information available on the use of gemcitabine in patients with hepatic impairment, therefore, used with caution. If bilirubin  $> 1.5 \times \text{ULN}$ , consider reducing dose to  $800 \text{ mg/m}^2$  (consultant decision).

### • Other toxicities

For all other toxicities, including stomatitis and diarrhoea, manage as per the following table:

Toxicity grade	Gemcitabine dose
1	100%
2	Delay until $\leq$ grade 1 then 100%
3	Delay until $\leq$ grade 1 then 75%
4	Delay until $\leq$ grade 1 then 50%

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

### • Rare or serious side effects

Myelosuppression

Infertility

Haemolytic uraemic anaemia\*

Interstitial pneumonitis, ARDS

Cardiotoxicity

Hepatotoxicity

Gemcitabine should be discontinued at the first sign of microangiopathic haemolytic anaemia (such as rapidly falling haemoglobin with concomitant thrombocytopenia, elevated bilirubin, creatinine, blood urea nitrogen or LDH. Renal failure may not be reversible with discontinuation of therapy, dialysis may be required.

- **Frequently occurring side effects**

Nausea and vomiting  
Myelosuppression  
Mucositis, stomatitis  
Diarrhoea, constipation  
Peripheral neuropathy  
Oedema  
Haematuria  
Influenza like symptoms  
Rash  
Peripheral neuropathy

- **Other side effects**

Raised transaminases  
Headache  
Alopecia  
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.

Gemcitabine is a radiosensitiser.

**Additional comments**

Nil

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**References**

- Summary of Product Characteristics Gemcitabine (Lilly) accessed 25 June 2014 via [www.medicines.org.uk](http://www.medicines.org.uk)
- Burris HA, Moore MJ, Andersen J, Green MR, Rothenberg ML, Modiano MR, et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: A randomized trial. J Clin Oncol 1997; 15 (6): 2403-2413.
- Allwood M, Stanley A, Wright P, editors. The cytotoxics handbook. 4<sup>th</sup> ed. Radcliffe Medical Press. 2002.

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