Gemcitabine (600mg/m^2) and RT Therapy – 7day

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Treatment of patients with localized unresectable adenocarcinoma of the pancreas	C25	00559a	Hospital

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Gemcitabine is administered on day 1 of a 7 day cycle prior to radiotherapy for 6 consecutive weeks (total number of doses is 6) according to the treatment table below.

Facilities to treat anaphylaxis MUST be present when gemcitabine is administered.

Treatment Table for Gemcitabine:

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	Gemcitabine	600mg/m^2	IV infusion	250ml NaCl 0.9% over 30 mins	Repeat every 7 days for 6 weeks

Summary table for Administration of Gemcitabine and Radiotherapy:

Week	Monday Day 1	Tuesday Day2	Wednesday Day 3	Thursday Day 4	Friday Day 5
1	**Gemcitabine** & Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy
2	**Gemcitabine** & Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy
3	**Gemcitabine** & Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy
4	**Gemcitabine** & Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy
5	**Gemcitabine** & Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy
6	**Gemcitabine** & Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy	Radiotherapy

ELIGIBILITY:

- Indications as above
- ECOG 0-2

EXCLUSIONS:

- Hypersensitivity to gemcitabine or any of the excipients
- Breast feeding

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist

TESTS:

Baseline tests:

- FBC, renal and hepatic profile

Regular tests:

- FBC, renal and hepatic profile prior to each cycle

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test(s) as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant.

Table 1: Dose Modification for Gemcitabine

Dose level	Recommended dose of Gemcitabine (mg/m^2)
0	600
-1	480
-2	380
-3	Discontinue treatment

Haematological:

Table 2: Dose Modifications for gemcitabine for haematological toxicity

ANC (x 10^9/L)		Platelet count (x 10^9/L)	Recommended dose of Gemcitabine
≥1	and	≥50	100 %
<1	or	<50	Delay dose until ANC ≥1 and platelets >50 then restart at one dose level reduction (Table 1)
Any incidence of febrile neutropenia			Delay until ANC ≥ 1 and restart at one dose level reduction.

Renal and Hepatic Impairment:

Table 3: Dose Modification of gemcitabine in Renal and Hepatic Impairment

Renal Impairment		Hepatic Impairment
CrCl (ml/min)	**Dose**	AST elevations do not seem to cause dose limiting toxicities. If bilirubin > 27 micromol/L, consider dose reduction. Clinical decision
≥30	100%	
<30	Consider dose reduction clinical decision	

Management of Adverse Events:

Table 4: Dose Modification of Gemcitabine for Adverse Events

Adverse reactions	Recommended dose modification
Grade 3 Non-haematological toxicity (except nausea/vomiting)	Delay until recovery and reduce by one dose level.
Grade 4 non-hematologic toxicity	Delay until recovery and reduce by one dose level. Consideration may be given to resuming treatment at one dose level reduction after recovery to ≤ Grade 2
Severe cutaneous adverse reactions (SCARs) e.g. Stevens-Johnson syndrome (SJS),toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalised exanthematous pustulosis (AGEP)	Discontinue treatment
Note: Doses delayed because of toxicity should not be administered at a later time	

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

Gemcitabine: Low **(Refer to local policy).**

PREMEDICATIONS: None usually required

OTHER SUPPORTIVE CARE: No specific recommendations

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

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

- **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated appropriately.
- **Pulmonary Toxicity**: Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.
- **Cardiovascular:** Due to the risk of cardiac and/or vascular disorders with gemcitabine, particular

caution must be exercised with patients presenting a history of cardiovascular events.

- **Irreversible renal failure** associated with haemolytic uraemic syndrome may occur rarely with gemcitabine. Use caution with pre-existing renal impairment.

DRUG INTERACTIONS:

- Current drug interaction databases should be consulted for more information.

REFERENCES:

1. Loehrer PJ Sr, Feng Y, Cardenes H, et al. Gemcitabine alone versus gemcitabine plus radiotherapy in patients with locally advanced pancreatic cancer: an Eastern Cooperative Oncology Group trial. *J Clin Oncol*. 2011;29 (31):4105–4112. doi:10.1200/JCO.2011.34.8904
2. Gemcitabine 40 mg/ml Concentrate for Solution for Infusion Summary of Product Characteristics Last updated: 18-Apr-19. Accessed June 2021. Available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2059-039-004_18042019163629.pdf
3. Dosage Adjustment for Cytotoxics in Renal Impairment January 2009; North London Cancer Network.
4. Dosage Adjustment for Cytotoxics in Hepatic Impairment January 2009;North London Cancer Network.

Version	Date	Amendment	Approved By
1	15/05/2019		Prof Ray McDermott
2	23/06/2021	Reviewed	Prof Maccon Keane
3	07/11/2025	Updated adverse events table (Table 4) to include information on SCARs.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.