GEMCITABINE weekly Pancreatic (Adjuvant and Metastatic)

DRUG ADMINISTRATION SCHEDULE

Day	Drug	Dose	Route	Diluent & Rate
Day 1	Sodium Chloride 0.9%	250/500ml	Infusion	Fast Running
	Ondansetron	8mg	Oral	
	Gemcitabine	**1000mg/m^2**	**Intravenous**	250ml 0.9% Sodium Chloride over 30minutes
Day 8	Sodium Chloride 0.9%	250/500ml	Infusion	Fast Running
	Ondansetron	8mg	Oral	
	Gemcitabine	**1000mg/m^2**	**Intravenous**	250ml 0.9% Sodium Chloride over 30minutes
Day 15	Sodium Chloride 0.9%	250/500ml	Infusion	Fast Running
	Ondansetron	8mg	Oral	
	Gemcitabine	**1000mg/m^2**	**Intravenous**	250ml 0.9% Sodium Chloride over 30minutes
Day 22 SEE BELOW	Sodium Chloride 0.9%	250/500ml	Infusion	Fast Running
	Ondansetron	8mg	Oral	
	Gemcitabine	**1000mg/m^2**	**Intravenous**	250ml 0.9% Sodium Chloride over 30minutes

CYCLE LENGTH AND NUMBER OF DAYS

Adjuvant Treatment:
Given once weekly for three (3) consecutive weeks out of every 4 weeks, i.e. Twenty-eight (28) day cycle, with treatment on days 1, 8 and 15 (rest on day 21) for 6 (SIX) cycles. For adjuvant treatment – no treatment is given on day 22 on any cycle.

Metastatic Disease
For the **first cycle only,** gemcitabine is given on day 22 which is equivalent to once weekly for up to 7 weeks - **To simplify administration (and improve tolerability of regimen) – some centres have decided to omit day 22 on all cycles for metastatic patients.**

From cycle two onwards, no chemotherapy is given on day 22 i.e. it is given as per adjuvant protocol: once weekly for three (3) consecutive weeks out of every 4 weeks, e.g. one cycle every 28 days. Treatment given on days 1, 8 and 15.

APPROVED INDICATIONS

Pancreatic adenocarcinoma, adjuvant and metastatic.

PREMEDICATION

As above

RECOMMENDED TAKE HOME MEDICATION

Metoclopramide 10 mg three times daily as required
Suggested antiemetic regimen - may vary with local practice. See CINV policy for more details

INVESTIGATIONS / MONITORING REQUIRED

Pre-treatment –
Full blood count, urea and electrolytes, liver function tests, baseline radiology (CXR/CT). Repeat radiology after 2 cycles
Prior to each cycle - FBC, U&Es, LFTs as required

ASSESSMENT OF RESPONSE

Metastatic: Tumour size and patient symptomatic response

REVIEW BY CLINICIAN

To be reviewed by either a Nurse, Pharmacist or Clinician before every cycle.

NURSE / PHARMACIST LED REVIEW

On cycles where not seen by clinician.

ADMINISTRATION NOTES

Gemcitabine is a radiation sensitiser and should therefore be used in caution with radiotherapy.

EXTRAVASATION *See NCA/Local Policy*

TOXICITIES

- Myelosuppression
- Nausea and vomiting
- Haematuria
- Dizziness during infusion
- Oedema/peripheral oedema
- Flu like symptoms
- Rarely pulmonary effects e.g. ARDS
- Lethargy
- Mild Alopecia

DOSE MODIFICATION / TREATMENT DELAYS Haematological Toxicity:

FBC on day of treatment

ANC		Platelet Count	% full dose
> 1.0	and	> 100,000	100%
0.5 – 1.0	and/or	50,000 - 100,000	75%
< 0.5	and/or	< 50,000	hold

NB
Week 1: if ANC < 1.0 & Platelets < 100,000 then Chemotherapy delayed 1 week
Weeks 2 & 3: Dose reduce as protocol above, if < 0.5 then the patient misses that dose and it is not replaced, carry on to the following week or the next course of chemotherapy as planned.

If Hb < 10 & patient symptomatic may need blood transfusion, but may proceed with chemotherapy as planned if performance status (PS) stable.
If pre-treatment U&Es & LFTs abnormal, delay treatment one week and discuss with Oncologist as may need dose reduction.

Non-Haematological Toxicity
If PS deteriorates to 3 or 4 and on assessment patient is more symptomatic withhold treatment and discuss with Oncologist

Renal or Hepatic impairment
- Gemcitabine should be used with caution in patients with renal or hepatic impairment.
- IF ALT > 3ULN or ALP > 3ULN or bilirubin >1.5ULN, DO NOT GIVE and consult with prescriber before proceeding
- Contra-indicated in severe renal failure (CrCl < 30ml/min) (Wright equation or measured GFR)
- Patients with pre-existing renal impairment should be monitored closely for haemolytic uremic syndrome

TREATMENT LOCATION
Can be given at Cancer Centre or Cancer Unit

REFERENCES:
1. Burris HA III, Moore MJ, Anderson J *et al*. (1997) Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. *J Clin Oncol*. **15**: 2403-13.
2. Neoptolemos JP, Stocken DD, Freiss H, et al. A randomized trial of chemoradiotherapy and chemotherapy after resection of pancreatic cancer. *N Engl J Med.* 2004;350:1200–1210 ESPAC-1
3. Regine WF, Winter KW, Abrams R, et al. RTOG 9704: A phase III study of adjuvant pre- and post chemoradiation (CRT) 5-FU vs. gemcitabine (G) for resected pancreatic adenocarcinoma. *J Clin Oncol.* 2006;24:18S.CONKO-001
4. J. Neoptolemos et al. ESPAC-3(v2): A multicenter, international, open-label, randomized, controlled phase III trial of adjuvant 5-fluorouracil/folinic acid (5-FU/FA) versus gemcitabine (GEM) in patients with resected pancreatic ductal adenocarcinoma. J Clin Oncol 27:18s, 2009 (suppl; abstr LBA4505)

Document Control

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Summary of Changes	1.1	Reformatted from old NCN/CCA version
	1.2a	Amendments to clarify schedule.
	1.3	Protocol reviewed and reissued, Antiemetic advice updated
	1.4	Updated against Chemocare protocol