

Indication	First line therapy with concurrent radiotherapy for patients with muscle invasive bladder cancer.
Treatment Intent	Radical
Frequency and number of cycles	One 28-day cycle with concurrent radiotherapy.
Monitoring Parameters pre-treatment	<ul style="list-style-type: none"> • Virology screening: All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • FBC, U&Es and LFTs on Day 1, 8, 15 and 22. • If WCC >3.0, neutrophils >1.5, platelets >100 continue with treatment, if parameters not met defer by one week and discuss with consultant. • Hepatic impairment: There is limited information about use of gemcitabine in hepatic impairment, therefore use with caution. If total bilirubin < 27µmol/L: no dose adjustment is needed. Total bilirubin >= 27µmol/L: either start at 80mg/m² and increase the dose if tolerated or start with full dose with active monitoring. • Renal impairment: If CrCl <30ml/min d/w consultant, clinical decision. • Adverse reactions: <ul style="list-style-type: none"> ○ Posterior Reversible Encephalopathy Syndrome (PRES) has been rarely reported with gemcitabine. In patients developing PRES, treatment of specific symptoms including control of hypertension is recommended along with discontinuation of gemcitabine. ○ Haemolytic uraemic syndrome. Gemcitabine should be discontinued at the first signs of any evidence of microangiopathic haemolytic anaemia, such as rapidly falling haemoglobin with concomitant thrombocytopenia, elevation of serum bilirubin, serum creatinine, blood urea nitrogen, or LDH. ○ Capillary leak syndrome. Gemcitabine should be discontinued and supportive measures implemented if capillary leak syndrome develops during therapy. Capillary leak syndrome can occur in later cycles and has been associated in the literature with adult respiratory distress syndrome. • Dose Modification: Dose reduction should be considered if grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&V and alopecia). Delay until resolution of toxicity to <= grade 1. • Common drug interactions (for comprehensive list refer to BNF/SPC): No specific interaction studies have been performed. • Driving: gemcitabine may cause drowsiness, patients should be advised to avoid driving or operating machinery until they establish if they are affected.
References	SPC accessed online 11.08.2022 NWCS protocol SWSCN protocol https://pubmed.ncbi.nlm.nih.gov/21205754/ Lancet Oncology Dose recommendations for anticancer drugs in patients with renal or hepatic impairment <i>Lancet Oncol</i> 2019 ; 20: e201–08.

NB For funding information, refer to CDF and NICE Drugs Funding List

Protocol No	URO-037	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V1	Written by	M.Archer
Supersedes version	New protocol	Checked by	C.Waters M.Capomir
Date	04.10.2022	Authorising consultant (usually NOG Chair)	C.Thomas

1 x 28-day cycle

Day	Drug	Dose	Route	Infusion Duration	Administration
1, 8, 15 and 22	Metoclopramide	20mg	PO		
	GEMCITABINE	100mg/m²	IV	30mins	2-4 hours prior to radiation In 250ml 0.9% NaCl
TTO	Drug	Dose	Route	Directions	
	Metoclopramide	10mg	PO	10mg TDS when required (max. 30mg per day including 20mg pre-chemo dose). Do not take for more than 5 days continuously.	

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