GEMCITABINE CISPLATIN

INDICATION (ICD10) C23

1. Advanced cholangiocarcinoma gallbladder and ampullary cancer (unlicensed)
2. Unknown primary if appropriate (unlicensed)

PS 0, 1, 2

REGIMEN

Day 1 Prehydration
CISPLATIN 25mg/m^2 in #ml sodium chloride 0.9% IV infusion over 60 minutes
GEMCITABINE 1000mg/m^2 in #ml sodium chloride 0.9% IV infusion over 30 minutes
Posthydration

Day 8 Prehydration
CISPLATIN 25mg/m^2 in #ml sodium chloride 0.9% IV infusion over 60 minutes
GEMCITABINE 1000mg/m^2 in #ml sodium chloride 0.9% IV infusion over 30 minutes
Posthydration

diluent and diluent volume for dose prescribed as per national standardised product specification or licensed dose

CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 21 days for 8 cycles

ANTI-EMETICS

Moderate risk days 1 and 8

CONCURRENT MEDICATION REQUIRED

Cisplatin	Ensure adequate pre and post hydration. If urine output is <100ml/hour or if patient gains >2kg in weight during IV administration post cisplatin give 20-40mg furosemide PO/IV.

EXTRAVASATION AND TYPE OF LINE / FILTERS

Cisplatin - exfoliant
Gemcitabine – neutral

No filters required
Central or peripheral line

INVESTIGATIONS

Blood results required before SACT administration
FBC every dose, U&E, LFTs and creatinine every cycle
Neutrophils x 10^9/L ≥1.5
Platelets x 10^9/L ≥100
GFR assessed using EDTA result or calculated creatinine clearance at the Consultant's discretion.
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Cisplatin	Nephrotoxicity – ensure adequate pre and post hydration is prescribed. Ototoxicity – assess patient for tinnitus or hearing abnormalities.
Gemcitabine	Diarrhoea – see dose modifications, treat with loperamide or codeine Mucositis – see dose modifications, use routine mouthcare

INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
(not exhaustive list check SPC/BNF/Stockleys)

Cisplatin	Aminoglycosides increased risk of nephrotoxicity and ototoxicity. Renal function should be well monitored and audiometric tests as required. Cisplatin can cause a decrease in phenytoin serum levels. This may lead to reappearance of seizures and may require an increase of phenytoin dosages.

DOSE MODIFICATIONS
Haematological

Neutrophils >1.5x10^9/L and platelets >100x10^9/L	give 100% dose
Neutrophils 1.0-1.5x10^9/L or platelets <100x10^9/L	Discuss with consultant
Neutrophils <1.0x10^9/L or platelets <100x10^9/L	Day 1 delay treatment Day 8 platelets <100x10^9/L omit gemcitabine treatment, and consider giving 75% gemcitabine dose subsequent cycles

Non-haematological
If patient complains of tinnitus, tingling of fingers and/or toes, discuss with SpR or Consultant before administration.

Hepatic impairment
Cisplatin
No need for dose adjustment

Gemcitabine

Bilirubin >27µmol/L	initiate treatment with 80% dose

Renal impairment
Cisplatin

CrCl >60ml/min	give 100% dose
CrCl 50-59ml/min	give 75% dose
CrCl 40-49ml/min	give 50% dose (curative intent) not recommended (palliative intent)
CrCl <40ml/min	not recommended

Gemcitabine
No need for dose adjustment

REFERENCES
1. J.W Valle et al; 2009 ASCO meeting Abstract 4503; J Clin Oncol 27:15s 2009(suppl;abstr 4503)
2. J.W Valle et al; ABC-02 trial; NEJM 8.4.10: Vol 362:1273-81