GEMCITABINE PACLITAXEL albumin bound

INDICATION (ICD10) C25

Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (NAB2)

1. The first line treatment of untreated metastatic pancreatic cancer only if other oxaliplatin or irinotecan combination chemotherapies are unsuitable and they would otherwise have gemcitabine monotherapy. PS 0 or 1. (TA476)
2. Gemcitabine and paclitaxel albumin combination chemotherapy for the treatment of locally advanced non-metastatic pancreatic adenocarcinoma cancer, and is either completely treatment naive for systemic therapy for pancreatic cancer OR has received prior systemic anti-cancer therapy as neoadjuvant, or adjuvant therapy and this treatment was completed at least 6 months previously. PS 0 or 1. (unlicensed)

REGIMEN

Days 1, 8 and 15
PACLITAXEL ALBUMIN BOUND 125mg/m^2 IV infusion over 30 minutes
GEMCITABINE 1000mg/m^2 infusion in #ml sodium chloride 0.9% IV infusion over 30 minutes

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

CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 28 days until disease progression or not tolerated

ANTI-EMETICS

Low risk days 1, 8 and 15

CONCURRENT MEDICATION REQUIRED

Gemcitabine	None required
Paclitaxel albumin bound	None required

EXTRAVASATION AND TYPE OF LINE / FILTERS

Gemcitabine – neutral
Paclitaxel albumin bound – vesicant

Administer palitaxel-albumin bound via a standard giving set with a 15micron (µm) filter
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 on day 1, ≥1.0 on day 8, see dose modifications table on day 15
Platelets x 10^9/L ≥100 on day 1, ≥75 on day 8, see dose modifications table on day 15
Hba1c baseline
Random glucose every cycle
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Gemcitabine	Diarrhoea – see dose modifications, treat with ,loperamide or codeine Mucositis – see dose modifications, use routine mouthcare
Paclitaxel albumin-bound	Hypersensitivity - discontinue immediately Bone marrow suppression Peripheral neuropathy Sepsis Pneumonitis

DOSE MODIFICATIONS

Dose Level	Paclitaxel-albumin bound dose (mg/m^2)	Gemcitabine dose (mg/m^2)
Full dose	125	1000
1st dose level reduction	100	800
2nd dose level reduction	75	600
If additional dose reduction required	Discontinue treatment	Discontinue treatment

Haematological

Dose modifications for neutropenia and/or thrombocytopenia at the start of a cycle or within a cycle for patients with pancreatic adenocarcinoma

Cycle day	ANC count x10^9/L		Platelet count x10^9/L	Paclitaxel-albumin bound dose	Gemcitabine dose
Day 1	<1.5	OR	<100	Delay doses until recovery	
Day 8	≥0.5 but <1.0	OR	≥50 but <75	Reduce doses 1 dose level	
	<0.5	OR	<50	Withhold doses	
Day 15: If day 8 doses were given without modification:					
Day 15	≥0.5 but <1.0	OR	≥50 but <75	Treat with day 8 dose level and follow with WBC growth factors OR reduce doses 1 dose level from day 8 doses	
	<0.5	OR	<50	Withhold doses	
Day 15: If day 8 doses were reduced:					
Day 15	≥1.0	AND	≥75	Return to the day 1 dose levels and follow with WBC growth factors OR treat with same doses as day 8	
	≥0.5 but <1.0	OR	≥50 but <75	Treat with day 8 dose levels and follow with WBC Growth Factors OR reduce doses 1 dose level from day 8 doses	
	<0.5	OR	<50	Withhold doses	
Day 15: If day 8 doses were withheld:					
Day 15	≥1.0	AND	≥75	Return to day 1 dose levels and follow with WBC growth factors OR Reduce doses 1 dose level from day 1 doses	
	≥0.5 but <1.0	OR	≥50 but <75	Reduce 1 dose level and follow with WBC growth factors OR reduce doses 2 dose levels from day 1 doses	
	<0.5	OR	<50	Withhold doses	

Non-haematological

Adverse drug reaction (ADR)	Paclitaxel albumin-bound dose	Gemcitabine dose
Febrile neutropenia: grade 3 or 4	Withhold doses until fever resolves and ANC ≥1.5; resume at next lower dose level	
Peripheral neuropathy: grade 3 or 4	Withhold dose until improves to ≤grade 1; resume at next lower dose level	Treat with same dose
Cutaneous toxicity: grade 2 or 3	Reduce to next lower dose level; discontinue treatment if ADR persists	
Gastrointestinal toxicity: grade 3 mucositis or diarrhoea	Withhold doses until improves to ≤grade 1; resume at next lower dose level	

Hepatic impairment

Gemcitabine

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

Paclitaxel-albumin bound

Total bilirubin >1.0 to ≤1.5xULN and AST ≤10xULN	no dose adjustments required.
Total bilirubin >1.5 to ≤5xULN and AST ≤10xULN	give 80% dose The reduced dose may be escalated to the dose for patients with normal hepatic function if the patient is tolerating the treatment for at least two cycles.

Renal impairment

Gemcitabine

No need for dose adjustment

Paclitaxel-albumin bound

CrCl ≥30ml/min	No dose reduction

REFERENCES

1. SPC December 2014
2. Blueteq criteria