

# BCCA Protocol Summary for Palliative Therapy for Germ Cell Cancers Using Paclitaxel and Gemcitabine

**Protocol Code** UGUTAXGEM

**Tumour Group** Genitourinary

**Contact Physician** Dr Nevin Murray

## ELIGIBILITY:

- Relapsed germ cell cancers not amenable to cure with surgery or chemotherapy
- Cisplatin-refractory (failed during 1<sup>st</sup>-line EP/BEP or after 2<sup>nd</sup>-line VIP/VEIP)
- Patients relapsed after BMT are potentially eligible
- A BCCA "Individual Use of Benefit Drug List Medication for an Undesignated Indication" form with appropriate clinical information for each patient must be approved.

## EXCLUSIONS:

- PS 3-4
- Motor neuropathy
- ANC **less than** 1.5, PI **less than** 100, AST **greater than** 4xULN, Bili **greater than** 35, or Creat **greater than** 180

## TESTS:

- Weekly CBC; monitor creat, LFTs, AFP, HCG, neuropathy each cycle
- Relevant imaging for response q8weeks (baseline and alternate cycles)

## PREMEDICATIONS:

- **Paclitaxel must not be started unless the following drugs have been given:**
  - 45 minutes prior to Paclitaxel:
    - Dexamethasone 20 mg IV in 50 mL NS over 15 minutes
  - 30 minutes prior to Paclitaxel:
    - Diphenhydramine 50 mg IV and Ranitidine 50 mg IV in 50 mL NS over 20 minutes (compatible up to 3 hours when mixed in bag)
- Additional antiemetics not usually required.

## TREATMENT:

- Cycle length four weeks, repeat every 28 days x 2 - 6 cycles.
- Discontinue if no response after 2 cycles.

Drug	Dose	BCCA Administration Guideline
Paclitaxel	110 mg/m <sup>2</sup> (d1, 8, 15)	IV in 500 mL* NS over 1 hour (use non-PVC equipment, in-line filter)
Gemcitabine	1,000 mg/m <sup>2</sup> (d1, 8, 15)	IV in 250 mL NS over 30 min

\*use 250 mL for doses less than 150 mg

## DOSE MODIFICATIONS:

### 1. Hematological

ANC (x10 <sup>9</sup> /L)		Platelets (x10 <sup>9</sup> /L)	Dose (both drugs)*
greater than or equal to 1.5	and	greater than or equal to 75	100% of previous cycle
1.0-1.49	and/or	50-74	75% of previous cycle
0.5-0.99	and/or	25-49	50% of previous cycle
less than 1.0	and/or	less than 25	Omit (d8) or delay (d1) **

\* a dose reduction for granulocytopenic fever or thrombocytopenia within a cycle results in a reduction of 25% in the start dose of the next cycle

\*\* if day 15, omit and start next cycle on day 22 instead of day 29

### 2. Gastrointestinal Toxicities

Grade	Stomatitis	Diarrhea	Dose Gemcitabine
1	Painless ulcers, erythema or mild soreness	Increase of 2-3 stools/day or mild increase in loose watery colostomy output	100%
2	Painful erythema, edema, or ulcers but can eat	Increase of 4-6 stools, or nocturnal stools or mild increase in loose watery colostomy output	Omit until toxicity resolved then resume at 100%
3	Painful erythema, edema, or ulcers and cannot eat	Increase of 7-9 stools/day or incontinence, malabsorption; or severe increase in loose watery colostomy output	Omit until toxicity resolved then resume at 75%
4	Mucosal necrosis, requires parenteral support	Increase of 10 or more stools/day or grossly bloody diarrhea, or grossly bloody colostomy output or loose watery colostomy output requiring parenteral support; dehydration	Omit until toxicity resolved then resume at 50%.

### 3. Other Non-Hematological Toxicities: dose modifications recommended for

- LFTs greater than or equal to 2 x ULN
- nausea Grade 4
- myalgia/rash Grade 3
- other toxicities of Grade 2-4 severity (excluding alopecia)

For more details, consult Table 2 of the referenced article.

## PRECAUTIONS:

1. **Hypersensitivity:** Reactions are common with paclitaxel. See BCCA Hypersensitivity Guidelines.
2. **Extravasation:** Paclitaxel causes pain and tissue necrosis if extravasated. Refer to BCCA Extravasation Guidelines.
3. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
4. **Thrombocytopenia:** platelet support may be required as per local guidelines.
5. **Renal Dysfunction:** Irreversible renal failure associated with hemolytic uremic syndrome may occur with gemcitabine (rare). Use caution with pre-existing renal dysfunction.
6. **Pulmonary Toxicity:** Acute shortness of breath may occur. Discontinue treatment if gemcitabine-induced pneumonitis is suspected.

7. **Arthralgia and/or Myalgia:** if unrelieved by acetaminophen  $\pm$  codeine, try
  - Prednisone 10 mg po bid x 5 days starting 24 hours post-paclitaxel
  - Gabapentin 300 mg po on day before chemotherapy, 300 mg bid on treatment day, then 300 mg tid x 7-10 days
8. **Neuropathy:** Dose modification or discontinuation may be required (see BCCA Cancer Drug Manual).

**Call Dr. Dr Murray or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.**

Date activated: 01 Nov 2002

Date revised: 01 May 2009 (unsafe abbreviations and symbols replaced)

**Reference:**

1. Hinton S, Catalano P, Einhorn LH, et al. Phase II study of paclitaxel plus gemcitabine in refractory germ cell tumors (E9897): a trial of the Eastern Cooperative Oncology Group. J Clin Oncol 2002;20(7):1859-63 (Erratum in J Clin Oncol 2002;20(17):3754).