

BCCA Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using Paclitaxel

Protocol Code:

BRAVTAX

Tumour Group:

Breast

Contact Physician:

Dr. Karen Gelmon

ELIGIBILITY:

- First, second, or third line treatment of metastatic breast cancer patients with ECOG performance status 0, 1, or 2, and greater than 3 month life expectancy
- For more than 6 cycles, a BCCA “Compassionate Access Program” request must be approved.

TESTS:

- Baseline: CBC & diff, platelets, bilirubin, AST
- Before each treatment: CBC & diff, platelets
- If clinically indicated: bilirubin & AST

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:

Drug	Dose	BCCA Administration Guideline
Paclitaxel	175 mg/m ²	IV in 500 mL * NS over 3 hours (use non-PVC equipment, in-line filter)

*use 250 mL for doses less than 150 mg

- Repeat every 21 days x 6 cycles.
- **Discontinue** if no response after 2 cycles.

DOSE MODIFICATIONS:

1. Hematological

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose	Dose after Neutropenic Sepsis on Paclitaxel
greater than or equal to 1.5	and	greater than 90	175 mg/m ²	135 mg/m ²
1 - 1.4	or	70-90	135 mg/m ²	135 mg/m ²
less than 1.0	or	less than 70	delay	delay

2. Hepatic Dysfunction

Bilirubin (micromol/L)		AST	Dose (mg/m ²)
less than or equal to 25	and	less than 2 x ULN	175 mg/m ²
less than or equal to 25	and	greater than or equal to 2 x ULN with no liver metastases or greater than or equal to 5 x ULN with liver metastases	135 mg/m ²
25-50			75 mg/m ²
greater than 50			50 mg/m ²

ULN = upper limit of normal

- Arthralgia and/or myalgia: If arthralgia and/or myalgia of grade 2 (moderate) or higher is not relieved by adequate doses of NSAIDs or acetaminophen with codeine (e.g., **TYLENOL #3®**), a limited number of studies report a possible therapeutic benefit using:
 - 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 daysIf arthralgia and/or myalgia persist, reduce subsequent Paclitaxel doses to 135 mg/m².
- Neuropathy: Dose modification or discontinuation may be required (see BCCA Cancer Drug Manual).

PRECAUTIONS:

- Hypersensitivity**: Reactions to paclitaxel are common. See BCCA Hypersensitivity Guidelines.

<p><u>Mild</u> symptoms (e.g. mild flushing, rash, pruritus)</p>	<ul style="list-style-type: none"> ▪ complete Paclitaxel infusion. Supervise at bedside ▪ no treatment required
<p><u>moderate</u> symptoms (e.g. moderate rash, flushing, mild dyspnea, chest discomfort, mild hypotension)</p>	<ul style="list-style-type: none"> ▪ stop Paclitaxel infusion ▪ give IV Diphenhydramine 25-50 mg and Hydrocortisone IV 100 mg ▪ after recovery of symptoms resume Paclitaxel infusion at 20 mL/h for 5 minutes, 30 mL/h for 5 minutes, 40 mL/h for 5 minutes, then 60 mL/h for 5 minutes. If no reaction, increase to full rate. ▪ if reaction recurs, discontinue Paclitaxel therapy
<p><u>severe</u> symptoms (i.e. <u>one</u> or more of respiratory distress requiring treatment, generalised urticaria, angioedema, hypotension requiring therapy)</p>	<ul style="list-style-type: none"> ▪ stop Paclitaxel infusion ▪ give IV antihistamine and steroid as above. Add Epinephrine or bronchodilators if indicated ▪ discontinue Paclitaxel therapy

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.

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

Date Activated: N/A

Date Revised: 01 Jan 2012 (eligibility revised)