

# BC Cancer Protocol Summary for Palliative Therapy for Metastatic Breast Cancer using PACLitaxel

**Protocol Code:**

**BRAVTAX**

**Tumour Group:**

**Breast**

**Contact Physician:**

**Dr. Nathalie LeVasseur**

## 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 BC Cancer “Compassionate Access Program” request must be approved.

## TESTS:

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

## PREMEDICATIONS:

- **PACLitaxel must not be started unless the following drugs have been given:**
  - 45 minutes prior to PACLitaxel: dexamethasone 20 mg IV in NS 50 mL over 15 minutes
  - 30 minutes prior to PACLitaxel: diphenhydrAMINE 50 mg IV in NS 50 mL over 15 minutes and famotidine 20 mg IV in NS 100 mL over 15 minutes (Y-site compatible)
- **If hypersensitivity reactions occur, premedications for re-challenge include dexamethasone 20 mg PO given 12 hours and 6 hours prior to treatment, plus IV premedications given 30 minutes prior to PACLitaxel: dexamethasone 20 mg, diphenhydramine 50 mg, and H<sub>2</sub>-antagonist (e.g., famotidine 20 mg). If no hypersensitivity reactions occur, standard premedications (see above) will be used for subsequent PACLitaxel doses.**
- Additional antiemetics not usually required.

## TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
PACLitaxel	175 mg/m <sup>2</sup>	IV in NS 250 to 500 mL over 3 hours (use non-DEHP bag and non-DEHP tubing with 0.2 micron in-line filter)

- Repeat every 21 days **until disease progression or unacceptable toxicity.**
- **Discontinue** if no response after 2 cycles.

## DOSE MODIFICATIONS:

### 1. Hematological

ANC (x 10 <sup>9</sup> /L)		Platelets (x 10 <sup>9</sup> /L)	Dose	Dose after Neutropenic Sepsis on PACLitaxel
greater than or equal to 1.5	and	greater than or equal to 90	175 mg/m <sup>2</sup>	135 mg/m <sup>2</sup>
1.0 to less than 1.5	or	70 to less than 90	135 mg/m <sup>2</sup>	135 mg/m <sup>2</sup>
less than 1.0	or	less than 70	delay	delay

### 2. Hepatic Dysfunction

Bilirubin (micromol/L)		ALT	Dose (mg/m <sup>2</sup> )
less than or equal to 25	and	less than 2 x ULN	175 mg/m <sup>2</sup>
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 <sup>2</sup>
25 to 50			75 mg/m <sup>2</sup>
greater than 50			50 mg/m <sup>2</sup>

ULN = upper limit of normal

3. 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 to 10 days
- If arthralgia and/or myalgia persist, reduce subsequent PACLitaxel doses to 135 mg/m<sup>2</sup>.
4. Neuropathy: Dose modification or discontinuation may be required (see BC Cancer Drug Manual).

**PRECAUTIONS:**

**1. Hypersensitivity:** Reactions to PACLitaxel are common. See BC Cancer [SCDRUGRX](#).

<i>Mild</i> symptoms (e.g. mild flushing, rash, pruritus)	<ul style="list-style-type: none"><li>▪ complete PACLitaxel infusion. Supervise at bedside</li><li>▪ no treatment required</li></ul>
<i>moderate</i> symptoms (e.g. moderate rash, flushing, mild dyspnea, chest discomfort, mild hypotension)	<ul style="list-style-type: none"><li>▪ stop PACLitaxel infusion</li><li>▪ give IV diphenhydrAMINE 50 mg and Hydrocortisone IV 100 mg</li><li>▪ 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.</li><li>▪ if reaction recurs, discontinue PACLitaxel therapy</li></ul>
<i>severe</i> symptoms (i.e. <i>one</i> or more of respiratory distress requiring treatment, generalised urticaria, angioedema, hypotension requiring therapy)	<ul style="list-style-type: none"><li>▪ stop PACLitaxel infusion</li><li>▪ give IV antihistamine and steroid as above. Add epinephrine or bronchodilators if indicated</li><li>▪ discontinue PACLitaxel therapy</li></ul>

**2. Extravasation:** PACLitaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.

**3. Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.

Call Dr. [Nathalie LeVasseur](#) or tumour group delegate at (604) 930-2098 or 1-800-663-3333 with any problems or questions regarding this treatment program.