# GEMCITABINE & CARBOPLATIN

**For Triple Negative Breast Cancer**

## Drug Administration Schedule

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Sodium Chloride 0.9%</td>
<td>250/500ml</td>
<td>Infusion</td>
<td>Fast Running</td>
</tr>
<tr>
<td></td>
<td>Dexamethasone</td>
<td>8mg</td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ondansetron</td>
<td>8mg</td>
<td>Oral /Slow bolus/15 min infusion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gemcitabine</td>
<td>1000mg/m²</td>
<td>Intravenous</td>
<td>250ml 0.9% Sodium Chloride over 30 minutes</td>
</tr>
<tr>
<td></td>
<td>Carboplatin</td>
<td>AUC 5</td>
<td>IV Infusion</td>
<td>250ml 5% Glucose over 30 to 60 Minutes</td>
</tr>
<tr>
<td>Day 8</td>
<td>Sodium Chloride 0.9%</td>
<td>250/500ml</td>
<td>Infusion</td>
<td>Fast Running</td>
</tr>
<tr>
<td></td>
<td>Ondansetron or Metoclopramide</td>
<td>8mg or 10mg</td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gemcitabine</td>
<td>1000mg/m²</td>
<td>Intravenous</td>
<td>250ml 0.9% Sodium Chloride over 30 minutes</td>
</tr>
</tbody>
</table>

*Ondansetron IV must be infused over 15 minutes in patients over 65 years of age.

## Carboplatin Dosage

Dose (mg) = AUC x (GFR + 25)

Where the GFR is the non-corrected EDTA clearance. If estimated GFR is undertaken the Wright formula must be used with AUC 5. Avoid use of Cockcroft & Gault formulae as it is less accurate.

## Cycle Length and Number of Days

Administered every 21 days for up to 6 cycles then review.

## Approved Indications

- First-line therapy of advanced/ metastatic breast cancer for patients with triple negative disease
- Metastatic bladder cancer

## Premedication

As above

## Recommended Take Home Medication

Ondansetron 8mgs twice daily for 2 days
Dexamethasone 4mgs twice daily for 1 day
Metoclopramide 10mg three times daily as required

* Suggested antiemetic regimen - may vary with local practice. See CINV policy for more details

## Investigations / Monitoring Required

**Pre treatment** - Full blood count, urea and electrolytes, liver function tests, baseline radiology (CXR/ CT). Repeat radiology after 2 cycles
Check renal function before commencing platinum. Use EDTA or Wright formulae to calculate GFR.
**Prior to each cycle**
FBC, U/E’s, LFT’s as required; GFR double checked using Wright formulae
ASSESSMENT OF RESPONSE
Metastatic: Tumour size and patient symptomatic response

REVIEW BY CLINICIAN
To be reviewed by either a Nurse, Pharmacist or Clinician before every cycle.

NURSE / PHARMACIST LED REVIEW
On cycles where not seen by clinician.

ADMINISTRATION NOTES
Use caution if the patient is also receiving radiotherapy, as Gemcitabine is a radiation sensitiser

EXTRAVASATION See NCA/ Local Policy

TOXICITIES
Risk of hypersensitivity and anaphylaxis, particularly when used second-line, start within a few minutes of administration
Nausea and vomiting
Myelosuppression, particularly, thrombocytopenia, anaemia & neutropenia
Nephrotoxicity
Peripheral neuropathy
Otolological impairment, especially at 8000 Hz
Haematuria
Dizziness during infusion
Oedema/peripheral oedema
Rarely pulmonary effects e.g. ARDS Lethargy
Mild Alopecia

DOSE MODIFICATION / TREATMENT DELAYS Haematological Toxicity:
Proceed on Day 1 if PLT ≥ 100, ANC ≥ 1.5, WBC > 2.0
Proceed on Day 8 if PLT ≥ 50, ANC ≥ 1.0, WBC > 2.0
Note: If outside of the parameters for day 8, that dose is omitted.

If Hb < 10 & patient symptomatic will need blood transfusion, but may proceed with chemotherapy as planned if performance status (PS) stable

If pre-treatment U&E’s & LFT’s abnormal, delay treatment 1 week and discuss with Oncologist as may need dose reduction

<table>
<thead>
<tr>
<th>NCI CTC Grade</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>100% of both drugs</td>
</tr>
<tr>
<td>3 (except for nausea/ vomiting and alopecia) (see below for neurotoxicity)</td>
<td>Delay until recovery to baseline, then retreat at a reduced dose level of both drugs as deemed appropriate by the investigator.*</td>
</tr>
</tbody>
</table>

*Doses should remain reduced in subsequent cycles. Dose reductions are commonly 25%.
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**Neurotoxicity**

<table>
<thead>
<tr>
<th>NCI CTC Grade</th>
<th>Platinum Dose</th>
<th>Gemcitabine Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>50%*</td>
<td>100%</td>
</tr>
<tr>
<td>3</td>
<td>Omit</td>
<td>100%</td>
</tr>
<tr>
<td>4</td>
<td>Discontinue drug</td>
<td></td>
</tr>
</tbody>
</table>

*Doses should remain reduced in subsequent cycles.

**Renal impairment**

*Carboplatin* - If creatinine level increases by >20% from the result used to calculate GFR (or pre-treatment baseline if EDTA performed) discuss with consultant and consider repeating EDTA.

*Gemcitabine* - should be used with caution in patients with renal or hepatic impairment. Patients with pre-existing renal impairment should be monitored closely for hemolytic uremic syndrome

**TREATMENT LOCATION**

Can be given at Cancer Centre or Cancer Unit

**REFERENCES:**


**Document Control**

<table>
<thead>
<tr>
<th>Document Title:</th>
<th>Gem-Carbo-Split-Day-Breast-protocol-CRP16 B032</th>
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<tbody>
<tr>
<td>Document No:</td>
<td>CRP012 B032</td>
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<tr>
<td>Current Version:</td>
<td>1.0</td>
</tr>
<tr>
<td>Reviewer:</td>
<td>Chris Beck Chemotherapy Pharmacist Northern Cancer Alliance</td>
</tr>
<tr>
<td>Date Approved:</td>
<td>28.02.18</td>
</tr>
<tr>
<td>Approved by:</td>
<td>Steve Williamson Consultant Pharmacist Northern Cancer Alliance</td>
</tr>
<tr>
<td>Due for Review:</td>
<td>01.03.21</td>
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<tr>
<td>Summary of Changes:</td>
<td>1.0 Created from chemocare protocol – split day, AUC5, bladder indication added</td>
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