ABRAXANE (Nab-Paclitaxel)

**DRUG ADMINISTRATION SCHEDULE**

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Daily Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
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<tbody>
<tr>
<td>Day 1</td>
<td>Sodium Chloride 0.9%</td>
<td>100ml</td>
<td>Infusion</td>
<td>Fast Running</td>
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<tr>
<td></td>
<td><strong>Nab-Paclitaxel</strong></td>
<td><strong>260 mg/m²</strong></td>
<td><strong>Infusion</strong></td>
<td><strong>IV over 30 minutes</strong> (presented as a 5mg/ml solution)</td>
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**CYCLE LENGTH AND NUMBER OF DAYS**
Given every 21 DAYS for six cycles or until disease progression or unacceptable toxicities.

**APPROVED INDICATIONS**
Advanced or metastatic breast cancer who have failed first-line treatment for metastatic disease and for whom standard, anthracycline containing therapy is not indicated and for whom standard taxanes are considered unsuitable.

**ELIGIABILITY CRITERIA**
As above

**EXCLUSION CRITERIA**
- patients who have progressed on prior taxane therapy
- pregnancy or lactation
- severe hepatic dysfunction contraindicating nab-paclitaxel

**PREMEDICATION**
Antiemetics not usually required for single agent use.

**RECOMMENDED TAKE HOME MEDICATION**
- **1st line**: Metoclopramide 10 mg three times daily as required
- **2nd line**: Oral Ondansetron 8mg Twice Daily for 2 to 3 days

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

**INVESTIGATIONS / MONITORING REQUIRED**
Prior to each cycle - FBC, U&E’s, LFT’s as required
Assessment of cardiac function, e.g. ECHO/MUGA scan pre- treatment and alternative cycles if significant cardiac history, or previous anthracycline therapy.

**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.

**EXTRAVASATION** See NCA/ Local Policy
Nab-Paclitaxel causes pain and tissue necrosis if extravasated, therefore extreme care must be taken when infusion pumps are used to control rate of administration. The injection site must be regularly monitored during infusion.
ABRAXANE (Nab-Paclitaxel)

PREPARATION NOTES
Nab-paclitaxel must only be prepared in an approved pharmacy aseptic preparation laboratory according to the following protocol:

- Nab-paclitaxel is available in 100mg or 250mg vials.
  - 100 mg vial: Using a sterile syringe, 20 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion should slowly be injected into a vial of Abraxane over a minimum of 1 minute.
  - 250 mg vial: Using a sterile syringe, 50 ml of sodium chloride 9 mg/ml (0.9%) solution for infusion should slowly be injected into a vial of Abraxane over a minimum of 1 minute.
- The solution should be directed onto the inside wall of the vial. The solution should not be injected directly onto the powder as this will result in foaming.
- Once the addition is complete, the vial should be allowed to stand for a minimum of 5 minutes to ensure proper wetting of the solid. Then, the vial should gently and slowly be swirled and/or inverted for at least 2 minutes until complete resuspension of any powder occurs. The generation of foam must be avoided. If foaming or clumping occurs, the solution must stand for at least 15 minutes until foam subsides.
- The reconstituted suspension should be milky and homogenous without visible precipitates. If precipitates or settling are visible, the vial should be gently inverted again to ensure complete resuspension prior to use. Some settling of the reconstituted suspension may occur. Complete resuspension should be ensured by mild agitation before use.
- Calculate the exact total dosing volume of 5 mg/ml suspension required for the patient and inject the appropriate amount of reconstituted Abraxane into an empty, sterile, PVC or non-PVC type intravenous bag. The use of specialized DEHP-free solution containers or administration sets is not necessary to prepare or administer Abraxane infusions.

ADMINISTRATION NOTES
- A 15 µm filter should be used
- The incidence of hypersensitivity is much lower than other taxanes, however if hypersensitivity occurs, product should be discontinued immediately, symptomatic treatment should be initiated, and that patient should not be rechallenged with paclitaxel.
- Nab-paclitaxel is metabolized by CYP2C8 and CYP3A4; caution should be exercised when administering with drugs which are CYP2C8 or CYP3A4 inducers or inhibitors, e.g. amiodarone, cyclosporine, grapefruit juice, simvastatin etc.

TOXICITIES
Abraxane is an albumin-bound nanoparticle formulation of paclitaxel, which may have substantially different pharmacological properties compared to other formulations of paclitaxel. Abraxane should not be substituted for or with other paclitaxel formulations.
- Myelosupression, particularly thrombocytopenia, anaemia & neutropenia
- Alopecia
- Peripheral neuropathy
- Arthralgia or Myalgia
- Back pain on administration
- Cardiac toxicity has been reported rarely while patients receive nab-Paclitaxel.
ABRAXANE (Nab-Paclitaxel)

DOSE MODIFICATION / TREATMENT DELAYS

Haematological Toxicity:
- Delay 1 week if ANC <1.0 Platelets <100
- No dose modification for CTC grade I/II ANC
- Grade III/IV ANC → delay chemotherapy until recovered. On recovery give 220mg/m² dose

Non-haematological Toxicity:
- If PS deteriorates to Grade 3 or 4 and on assessment patient is more symptomatic withhold treatment and discuss with Oncologist

Sensory neuropathy
Patients who experience severe sensory neuropathy (CTC grade 3/4) during therapy should have the dose reduced to 220 mg/m² for subsequent courses. Following recurrence of severe sensory neuropathy, additional dose reduction to 180 mg/m².

TREATMENT LOCATION
Can be given at Cancer Centre or Cancer Unit

REFERENCES:
2. Abraxis Oncology. ABRAXANE® SPC Available at www.medicines.org.uk.
3. Gradishar et al; Significantly longer progression-free survival with nab-paclitaxel compared with Docetaxel.JCO27,number 22August 20093611-3619

Document Control

<table>
<thead>
<tr>
<th>Document Title:</th>
<th>CRP10 B027 Nab-Paclitaxel (abraxane) protocol</th>
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<td>Document No:</td>
<td>CRP09 B027</td>
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<tr>
<td>Current Version:</td>
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<tr>
<td>Reviewer:</td>
<td>Chris Beck Chemotherapy Pharmacist</td>
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<td>Northern Cancer Alliance</td>
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<td>Date Approved:</td>
<td>28.02.18</td>
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<tr>
<td>Approved by:</td>
<td>Steve Williamson Consultant Pharmacist</td>
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<td>Due for Review</td>
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<tr>
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<td>1.3 Protocol reviewed and reissued, Antiemetic advice updated</td>
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<tr>
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<td>1.4 In-line filter advice amended</td>
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<tr>
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<td>1.5 Document reviewed, preparation notes updated, NCA added.</td>
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