

## Chemotherapy Protocol

### BREAST CANCER

#### PACLITAXEL ALBUMIN BOUND

##### Regimen

- Breast Cancer – Paclitaxel Albumin Bound

##### Indication

- Paclitaxel albumin bound can be prescribed where;
  - there is a confirmed histological or cytological breast cancer
  - there is a confirmed severe paclitaxel hypersensitivity which precludes further exposure to paclitaxel (patients who have had a severe hypersensitivity reaction to docetaxel should have been switched to a trial of paclitaxel)
  - the patient is being switched to paclitaxel albumin bound from either paclitaxel or docetaxel to reduce the toxicity of treatment and / or to reduce the number of admissions required for administration of treatment during the COVID-19 pandemic
- Paclitaxel albumin bound will be used as a single agent or in combination for neo-adjuvant, adjuvant or metastatic disease (note that neo-adjuvant and adjuvant treatment are unlicensed)
- WHO Performance status 0, 1

##### Toxicity

Drug	Adverse Effect
Paclitaxel Albumin Bound	Neuropathy, hypersensitivity, arthralgia, back pain, alopecia, rash

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

##### Monitoring

###### *Drugs*

- FBC, U&E's and LFT's prior today one of the cycle.

##### Dose Modifications

The dose modifications listed are for haematological, liver and renal function only. Dose adjustments may be necessary for other toxicities as well.

In principle all dose reductions due to adverse drug reactions should not be re-escalated in subsequent cycles without consultant approval. It is also a general rule for chemotherapy that if a third dose reduction is necessary treatment should be stopped.

Please discuss all dose reductions / delays with the relevant consultant before prescribing, if appropriate. The approach may be different depending on the clinical circumstances. The following is a general guide only.

### Haematological

Prior to prescribing cycle one the following criteria must be met.

Criteria	Eligible Level
Neutrophil	equal to or more than $1.5 \times 10^9/L$
Platelets	equal to or more than $100 \times 10^9/L$

Consider blood transfusion if patient symptomatic of anaemia or has a haemoglobin of less than 8g/dL

Treatment should be delayed if the neutrophil count is less than  $1 \times 10^9/L$  and / or if the platelets are less than  $100 \times 10^9/L$ . If counts recover at this point treatment may continue at the same dose for a NCI-CTC grade 1 or 2 toxicity. For a NCI-CTC grade 3 or above toxicity reduce the dose to  $220 \text{mg}/\text{m}^2$ . If a second recurrence of a NCI-CTC grade 3 toxicity resume treatment on recovery using a dose of  $180 \text{mg}/\text{m}^2$ .

The treatment indication should be considered when deciding on dose reductions.

### Hepatic Impairment

Grade	ALT		Bilirubin	Dose
Moderate	less than 10xULN	and	1.25-2xULN	$200 \text{mg}/\text{m}^2$
Severe	less than 10xULN	and	2.01-5xULN	$130 \text{mg}/\text{m}^2$
Severe	greater than 10xULN	or	Greater than 5xULN	Do not use

In severe impairment if the initial dose of  $130 \text{mg}/\text{m}^2$  is tolerated consider increasing to  $200 \text{mg}/\text{m}^2$ .

### Renal Impairment

Drug	Creatinine Clearance (ml/min)	Dose (% of original dose)
Paclitaxel albumin bound	No information available	

### Other

#### Sensory Neuropathy

For those who experience a NCI-CTC grade 3 or above neuropathy allow symptoms to settle to NCI-CTC grade 1 or 2 and resume treatment at a dose of  $220 \text{mg}/\text{m}^2$ . Following a recurrence reduce the dose to  $180 \text{mg}/\text{m}^2$ .

For those who experience a NCI-CTC grade 2 neuropathy reduce the dose to  $220 \text{mg}/\text{m}^2$ . If the neuropathy recurs at NCI-CTC grade 2 this should be reduced to  $180 \text{mg}/\text{m}^2$ .

## [Regimen](#)

**21 day cycle – 6 cycles will be set in ARIA (the number of cycles may vary with indication)**

Drug	Dose	Days	Administration
Paclitaxel albumin bound	260mg/m <sup>2</sup>	1	Intravenous infusion over 30 minutes

## [Dose Information](#)

- Paclitaxel albumin bound will be dose banded in accordance with the national dose bands

## [Administration Information](#)

### *Extravasation*

- Paclitaxel albumin bound - vesicant

### Other

- The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer paclitaxel albumin bound may result in the formation of proteinaceous strands. Administer using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. Use of filters with a pore size less than 15 µm may result in blockage of the filter.

## [Additional Therapy](#)

- Antiemetics

No antiemetics are required prior to treatment

As take home medication on cycle 1 only;

- metoclopramide 10mg three times a day when required oral

- Gastric protection with a proton pump inhibitor or a H<sub>2</sub> antagonist may be considered in patients considered at high risk of GI ulceration or bleed.

## [References](#)

1. Gradishar WJ et al. Phase III trial of nanoparticle albumin bound paclitaxel compared compared with polyethylated castor oil based paclitaxel in women with breast cancer. J Clin Oncol 2005; 23:7794-7803.

## REGIMEN SUMMARY

### Paclitaxel Albumin Bound (Abraxane)

#### Cycle 1-day 1

1. Paclitaxel albumin bound 260mg/m<sup>2</sup> intravenous infusion over 30 minutes

Administration Instructions

The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer paclitaxel albumin bound may result in the formation of proteinaceous strands. Administer using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. Use of filters with a pore size less than 15 µm may result in blockage of the filter.

#### Take Home Medicines

2. Metoclopramide 10mg three times a day when required oral

Administration Instructions

Please supply 30 tablets or one original pack as appropriate

#### Cycle 2 onwards-day 1

3. Paclitaxel albumin bound 260mg/m<sup>2</sup> intravenous infusion over 30 minutes

Administration Instructions

The use of medical devices containing silicone oil as a lubricant (i.e. syringes and IV bags) to reconstitute and administer paclitaxel albumin bound may result in the formation of proteinaceous strands. Administer using an infusion set incorporating a 15 µm filter to avoid administration of these strands. Use of a 15 µm filter removes strands and does not change the physical or chemical properties of the reconstituted product. Use of filters with a pore size less than 15 µm may result in blockage of the filter.

## DOCUMENT CONTROL

Version	Date	Amendment	Written By	Approved By
1	Jan 2021	None	Dr Deborah Wright Pharmacist	Dr Chern Lee Consultant Medical Oncologist

This chemotherapy protocol has been developed as part of the chemotherapy electronic prescribing project. This was and remains a collaborative project that originated from the former CSCCN. These documents have been approved on behalf of the following Trusts;

Hampshire Hospitals NHS Foundation Trust  
NHS Isle of Wight  
Portsmouth Hospitals NHS Trust  
Salisbury Hospital NHS Foundation Trust  
University Hospital Southampton NHS Foundation Trust  
Western Sussex Hospitals NHS Foundation Trust

All actions have been taken to ensure these protocols are correct. However, no responsibility can be taken for errors which occur as a result of following these guidelines.