PROTOCOL

The Clatterbridge Cancer Centre NHS Foundation Trust

Systemic Anti Cancer Therapy Protocol

Paclitaxel Albumin (ABRAXANE) Breast Cancer

PROTOCOL REF: **MPHAALPABR**
(Version No. 1.1)

Approved for use in:

Breast cancer in the neoadjuvant, adjuvant or advanced/metastatic setting - when it is no longer safe to continue with paclitaxel or docetaxel **due to allergic reactions**, but taxanes are indicated.

OR

Interim COVID19 guidance – Paclitaxel albumin instead of either paclitaxel or docetaxel in neoadjuvant, adjuvant or advanced/metastatic setting- to reduce the toxicity of treatment and/or to reduce the number of admissions required for administration of treatment during the COVID19 crisis.

ECOG performance status 0 to 2 is required for both indications

*********Blueteq form required for both indications*********

Note: Paclitaxel albumin (Abraxane) is time consuming to prepare, therefore patients must be booked for a go ahead appointment the day before treatment to prevent delays.

Dosage:

Drug	Dose	Route	Frequency
Albumin paclitaxel (Abraxane)	260mg/m²	IV	Every 21 days

Neoadjuvant or adjuvant use – treatment is given to replace the planned number of taxane cycles.

Palliative treatment – continue until disease progression, or unacceptable toxicity with review after 6 cycles in total to ensure ongoing clinical benefit

Extravasation risk:

Albumin Paclitaxel (Abraxane) is a **VESICANT**

Refer to the CCC policy for the 'Prevention and Management of Extravasation Injuries'.

Emetogenic risk:

Mildly emetogenic.

Supportive treatments:

Metoclopramide 10mg tablets, to be taken up to three times a day as required for nausea and vomiting for maximum 5 consecutive days

For neoadjuvant/adjuvant patients:

- Weight <70kg – Filgrastim 300 micrograms s/c once a day for 7 days starting on day 3 of cycle
- Weight ≥ 70kg – Filgrastim 480 micrograms s/c once a day for 7 days starting on day 3 of cycle

Dosing in renal and hepatic impairment:

Renal	GFR ≥ 30ml/min- no dose adjustment required GFR <30ml/min or Haemodialysis - no need for dose adjustment is expected. Use with caution as not tested in this patient group.

Hepatic	Patients with hepatic impairment may be at increased risk of toxicity, particularly from myelosuppression. Mild hepatic impairment total bilirubin > 1 to ≤ 1.5 x ULN and AST ≤ 10 x ULN- no dose adjustments required. Moderate to severe hepatic impairment

	Total bilirubin > 1.5 to ≤ 5 x ULN and AST ≤ 10 x ULN)- 20% reduction in dose is recommended. The reduced dose may be escalated to full dose if the patient is tolerating the treatment for at least two cycles **Abraxane is not recommended in patients that have total bilirubin > 5 x ULN or AST > 10 x ULN.**

Interactions:

Paclitaxel toxicity may be increased with medicines known to inhibit either CYP2C8 or CYP3A4 (e.g. ketoconazole and other imidazole antifungals, erythromycin, fluoxetine, gemfibrozil, clopidogrel, cimetidine, ritonavir, saquinavir, indinavir, ritonavir and nelfinavir)- use with caution

Administering paclitaxel concomitantly with medicines known to induce either CYP2C8 or CYP3A4 (e.g. rifampicin, carbamazepine, phenytoin, efavirenz, nevirapine) is not recommended- paclitaxel efficacy may be compromised.

Refer to the SmPC for full details on interactions.

Treatment schedule:

Day	Drug	Dose	Route	Diluent and rate
1	**Dexamethasone**	**8mg**	**PO**	30 minutes before chemotherapy
	Albumin Paclitaxel (Abraxane)	**260mg/m^2**	**IV**	Administer over 30 minutes

Hypersensitivity: routine prophylaxis against infusion related reactions is not required with Paclitaxel Albumin (Abraxane). However, monitor during the infusion and treatment given if necessary (antihistamines, steroids etc.).

Please refer to the CCC Hypersensitivity; Management Prevention Policy

Main toxicities:

Cardiac and vascular disorders	Tachycardia, arrhythmia, supraventricular tachycardia are common
Haematological	Neutropenia, anaemia, thrombocytopenia,
Gastrointestinal	Nausea, vomiting, diarrhoea, constipation, mucositis

Musculoskeletal	Arthralgia, myalgia
Nervous system	Peripheral neuropathy
Hepatobiliary	Elevation of liver transaminases, alkaline phosphatase and bilirubin.
Skin and subcutaneous tissue disorders	Alopecia Allergic skin rash frequently associated with pruritus
General disorders and administration site conditions	Fatigue Infertility, early menopause

Investigations and treatment plan:

	Pre	Cycle 1	Cycle 2	Cycle 3	Cycle 4	Ongoing
Informed Consent	x					
Clinical Assessment	x		x		x	Alternate cycles or as clinically indicated
SACT Assessment (to include PS and toxicities)	x	x	x	x	x	Every cycle
On treatment review / Go ahead	x	x	x	x	x	Day before treatment
FBC	x	x	x	x	x	Every cycle
U&E & LFTs	x	x	x	x	x	Every Cycle
CT scan	x					3 monthly or as clinically indicated **for metastatic patients only**
Full observations	x					Repeat if clinically indicated
Weight recorded	x	x	x	x	x	Every cycle
Height	x					

Dose Modifications and Toxicity Management:

Haematological toxicity:

Proceed on **cycle 1 day 1** ONLY if-

ANC ≥ 1.5 x 10^9/L	Plt ≥ 100 x 10^9/L

Proceed on **day 1** of cycle 2 onwards if-

ANC ≥ 1.0 x 10^9/L	Plt ≥ 100 x 10^9/L

Delay 1 week on day 1 of cycle 2 onwards if-

ANC ≤ 0.9 x 10^9/L	Plt ≤ 99 x 10^9/L

These haematological guidelines assume that patients are well with good performance status, that other acute toxicities have resolved and the patient has not had a previous episode of neutropenic sepsis.

Non-haematological toxicity:

Neuropathy:

1st occurrence of grade 2 sensory neuropathy- dose reduced to 220 mg/m² for subsequent courses.

Recurrence of grade 2 sensory neuropathy- additional dose reduction should be made to 180 mg/m^2.

Grade 3 sensory neuropathy- hold treatment until resolution to Grade 1 or 2, followed by a dose reduction for all subsequent courses if continuing treatment.

References:

Abraxane 5 mg/ml powder for dispersion for infusion SmPC, Bristol-Myers Squibb Pharmaceuticals limited. Last updated 6th October 2021.

NAB1CV_v1.1 – Interim COVID19 Blueteq Form – Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) instead of either paclitaxel or docetaxel in breast cancer regimens (accessed 8th March 2023)

NAB1_v1.2 NHS England – Initial Funding Application Blueteq Form – Paclitaxel as albumin-bound nanoparticles (nab-paclitaxel) for breast cancer (accessed 8th March 2023)

Supplement to: Krens S D, Lassche, Jansman G F G A, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment. Lancet Oncol 2019; 20: e201–08.

Circulation/Dissemination

Date added into Q-Pulse	22nd June 2022
Date document posted on the Intranet	N/A

Version History

		Author name and designation	Summary of main changes
		Helen Flint	New Regimen Protocol V1.0
		Gabriella Langton **Breast SRG Pharmacist**	Routine protocol update V1.1