**Systemic Anti Cancer Treatment Protocol**

# Albumin Paclitaxel (ABRAXANE)

**PROTOCOL REF: MPHAALPABR**
**(Version No: 1.0)**

## Approved for use in:

Breast cancer - when no longer safe to continue with paclitaxel or docetaxel due to allergic reactions, but taxanes are indicated

ECOG performance status 0 to 2

**Exclusion criteria:**

Severe bone marrow depression

Severe hepatic impairment (AST >10 x ULN or bilirubin > 5 x ULN)

## Dosage:

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

For adjuvant patients – treatment is given to replace the planned number of docetaxel doses

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

Supportive treatments:

Domperidone 10mg tablets, to be taken up to three times a day as required

For 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

## Extravasation risk

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

## Administration:

| 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 mins |

**Hypersensitivity:** Premedication to prevent hypersensitivity reactions is generally not needed prior to the administration of albumin paclitaxel (Abraxane).

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

## Main Toxicities:

| | |
|---|---|
| **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<br>Allergic skin rash frequently associated with pruritus |
| **General disorders and administration site conditions** | Fatigue<br>Infertility, early menopause |

## Investigations:

| | Pre | Cycle 1 | Cycle 2 | Cycle 3 | Cycle 4 | Ongoing |
|---|---|---|---|---|---|---|
| Medical Assessment | X | | X | | X | Alternate cycles |
| Nursing Assessment | | X | X | X | X | Every cycle |
| FBC | X | | X | X | X | Every cycle |
| U&E & LFT | X | | X | X | X | Every cycle |
| CT scan | X | | | | | As clinically indicated for metastatic patients only |
| Informed Consent | X | | | | | |
| PS recorded | X | X | X | X | X | Every cycle |
| Toxicities documented | X | | X | X | X | |
| Weight recorded | X | X | X | X | X | Every cycle |

## Dose Modifications:

### Haematological toxicity

Proceed on day 1 if:-

| | |
|---|---|
| Platelets ≥ 100 x $10^9$/L | ANC ≥ 1.0 x $10^9$/L |

Delay 1 week on day 1 if:-

| | |
|---|---|
| Platelets ≤ 99 x $10^9$/L | ANC ≤ 0.9 x $10^9$/L |

### Non-haematological toxicity

**Hepatic Impairment:** No dose adjustment is necessary for patients with mild hepatic impairment.

Patients with moderate and severe hepatic impairment treated with albumin paclitaxel (Abraxane) may be at increased risk of toxicities known to paclitaxel.

Albumin paclitaxel (Abraxane) can be increased from 130 mg/m² up to 200 mg/m² in patients with severe hepatic impairment in subsequent cycles based on individual tolerance.

**Recommendations for Starting Dose in Patients with Hepatic Impairment:**

| Grade | AST | | Bilirubin | Abraxane Dose |
|---|---|---|---|---|
| **Moderate** | < 10 x ULN | AND | 1.25 to 2 x ULN | 200 mg/m² |
| **Severe** | < 10 x ULN | AND | 2.01 to 5 x ULN | 130 mg/m² |
| **Severe** | > 10 x ULN | OR | > 5 x ULN | Not recommended |

**Renal impairment:** No formal guidance, no dose reduction required in mild to moderate impairment.

**Neuropathy:** Patients who experience grade 2 sensory neuropathy during Albumin paclitaxel (Abraxane) therapy should have dosage reduced to 220 mg/m² for subsequent courses. For recurrence of grade 2 sensory neuropathy, additional dose reduction should be made to 180 mg/m$^2$. For 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 SmPC

Gradishar W et al, JCO 2005
Phase III trial of albumin bound paclitaxel