# PEMBROLIZUMAB (Keytruda) PACLITAXEL albumin-bound (nab-PACLITAXEL)

## INDICATION (ICD10) C50

*Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/)* (PEMB18)

1. The treatment of previously untreated locally advanced unresectable or metastatic triple negative breast cancer in patients with PD-L1 expression test results of immune cell (IC) <1% and a combined positive score (CPS) of 10 or more. PS 0 or 1. (TA801)

## REGIMEN (SC)

Days 1, 8 and 15 (**Pembrolizumab before all chemotherapy)**
PACLITAXEL ALBUMIN BOUND 100mg/m$^2$ IV infusion over 30 minutes

Day 1 PEMBROLIZUMAB 790mg subcutaneous* (4.8ml) over 2 minutes every 42 days

*Into the thigh or abdomen, avoiding the 5cm area around the navel

## REGIMEN (IV)

Days 1, 8 and 15 (**Pembrolizumab before all chemotherapy)**
PACLITAXEL ALBUMIN BOUND 100mg/m$^2$ IV infusion over 30 minutes

Day 1 PEMBROLIZUMAB 400mg in 100ml sodium chloride IV infusion over 30 minutes every 42 days

## CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 28 days
Pembrolizumab every 42 days until disease progression up to maximum 2 years
Paclitaxel-albumin bound until disease progression or unacceptable toxicity
(if one drug needs to be discontinued due to toxicity, the other may continue)

## ADMINISTRATION

Pembrolizumab SC - withdraw the required volume using a transfer needle (18-21G recommended). To avoid needle clogging, change the needle to a 25-30G, 13 mm hypodermic injection needle immediately prior to SC injection.
Do not administer other medicinal products for injection at the same site as the pembrolizumab.

## ANTI-EMETICS

Low risk days 1, 8 and 15

## CONCURRENT MEDICATION REQUIRED

None

## EXTRAVASATION AND TYPE OF LINE / FILTERS

Paclitaxel albumin bound – vesicant
Pembrolizumab IV – neutral

Paclitaxel albumin-bound administer via a standard giving set with a 15micron (µm) filter
Pembrolizumab IV administer via low protein binding 0.2 to 5micron in-line or add-on filter

Central or peripheral line

## INVESTIGATIONS

Blood results required before SACT administration
FBC every dose. U&E and LFTs every dose (unless no concerns on day 1, then every cycle
Neutrophils x $10^9$/L ≥1.0 day 1 (if not delay), ≥1.0 days 8 and 15 (if not omit paclitaxel albumin-bound clinician discretion)
Platelets x $10^9$/L ≥100 day 1 if not delay), ≥100 days 8 and 15 (if not omit paclitaxel albumin-bound clinician discretion)
Thyroid function* baseline, then every pembrolizumab cycle
Random cortisol baseline, then every pembrolizumab cycle (or as specified in Trust guideline)
Random glucose every pembrolizumab cycle
Hba1c baseline
Baseline weight and every cycle

## MAIN TOXICITES AND ADVERSE REACTIONS

| | |
|---|---|
| Paclitaxel albumin-bound | Hypersensitivity - discontinue immediately<br>Bone marrow suppression<br>Peripheral neuropathy<br>Sepsis<br>Pneumonitis |
| Pembrolizumab | Immune related toxicities - pneumonitis, colitis or hepatitis etc<br>Pembrolizumab SC skin reactions at site of administration route |

## DOSE MODIFICATIONS

### Haematolgical

Paclitaxel albumin-bound

| | | |
|---|---|---|
| Day 1<br>Neutrophils <1.0x$10^9$/l or platelets <100x$10^9$/l<br>Delay nab-paclitaxel until counts above these limits.<br>If time to neutrophil recovery is >7 days, once recovered reduce nab-paclitaxel dose.<br>If any case of neutropenic fever (neutrophils <0.5 x$10^9$/l with temp >38C°), once recovered reduce nab-paclitaxel dose. | First occurrence | 75mg/$m^2$ |
| | Second occurrence | 50mg/$m^2$ |
| | Third occurrence | Discontinue treatment |
| Days 8 and 15<br>Neutrophils <1.0x$10^9$/l or platelets <100x$10^9$/l<br>Delay nab-paclitaxel until counts above these limits.<br>If time to neutrophil recovery is >7 days, or any episode of platelets <50, once recovered reduce nab-paclitaxel dose. | First occurrence | 75mg/$m^2$ |
| | Second occurrence | Discontinue treatment |

### Non-haematological

| | | |
|---|---|---|
| Paclitaxel albumin-boundAny grade 2 or 3 toxicities | First occurrence | 75mg/$m^2$ |
| | Second occurrence | 50mg/$m^2$ |
| | Third occurrence | Discontinue treatment |

Pembrolizumab
Immune-related adverse reactions - refer to TV immune-oncology agent immune related adverse event clinical guideline.
If the drug-related toxicity does not resolve to grade 0-1 within 12 weeks after onset of toxicity, discontinuation is recommended.

**Hepatic impairment**

Paclitaxel albumin-bound

| | |
|---|---|
| Total bilirubin >1.0 to ≤1.5xULN and AST ≤10xULN) | no dose adjustments required. |
| Total bilirubin >1.5 to ≤5xULN and AST ≤10xULN) | give 80% dose<br>The reduced dose may be escalated to the dose for patients with normal hepatic function if the patient is tolerating the treatment for at least two cycles. |

Pembrolizumab

No dose adjustment is needed

**Renal impairment**

Paclitaxel albumin-bound

No dose adjustment is needed

Pembrolizumab

No dose adjustment is needed

**REFERENCES**

1. SPC
2. Blueteq criteria