PEGYLATED LIPOSOMAL DOXORUBICIN (Caelyx)

INDICATION (ICD10) C41, C49, C56

1. Second-line (or subsequent treatment of women with partially platinum-sensitive, platinum resistant or platinum refractory advanced ovarian cancer, and for women who are allergic to platinum based compounds.
2. Endometrial recurrence or metastatic 1st line if unable to have taxanes.
3. *Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/)* (PDL1)
   The treatment of sarcomas in patients with cardiac impairment requiring an anthracycline, 1st line indication or 2nd line indication (unlicensed).
4. Fibromatosis (local funding).

REGIMEN

Day 1 PEGYLATED LIPOSOMAL DOXORUBICIN 40mg/m^2 in 250ml* glucose 5% IV infusion
Cycle 1 infusion at a rate of 1mg/m^2 subsequent cycles over 60 minutes

* doses 90mg to 150mg in 500ml glucose 5%

CYCLE FREQUENCY AND NUMBER OF CYCLES

Ovarian, endometrial - every 28 days for up to 6-8 cycles
Sarcoma - every 28 days for up to 6 cycles

ANTI-EMETICS

Low emetic risk day 1

CONCURRENT MEDICATION REQUIRED

None

EXTRAVASATION AND TYPE OF LINE / FILTERS

Liposomal doxorubicin - exfoliant

Peripheral line

INVESTIGATIONS

Blood results required before SACT administration
FBC, U&E and LFTs every week
Neutrophils x 10^9/L ≥1.0
Platelets x 10^9/L ≥100
ECG (possible ECHO) required if patient has preexisting cardiac disease
CA125 baseline and day 1 every cycle (ovarian)
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Liposomal doxorubicin	Cardiotoxicity – monitor cardiac function. Liposomal doxorubicin may be stopped in future cycles if signs of cardiotoxicity eg cardiac arrhythmias, pericardial effusion, tachycardia with fatigue. Infusion related reactions – allergic or anaphylactic like reactions consider prophylaxis Palmar-plantar erythema - treat with steroids prednisolone 30mg od or dexamethasone 8mg od. Consider pyridoxine.

DOSE MODIFICATIONS

Liposomal doxorubicin maximum lifetime dose
= 400mg/m^2 (in patients with cardiac dysfunction or exposed to mediastinal irradiation)
= 450-550mg/m^2 (with normal cardiac function)

Haematological

Grade 1 ANC 1.5-1.9x10^9/l Platelets 75-150x10^9/l	Resume treatment with no dose reduction.
Grade 2 ANC 1.0-1.5x10^9/l Platelets 50-75x10^9/l	Wait until ANC ≥1.5 and platelets ≥75 redose with no dose reduction.
Grade 3 ANC 0.5-1.0x10^9/l Platelets 25-50x10^9/l	Wait until ANC ≥1.5 and platelets ≥75 redose with no dose reduction.
Grade 4 ANC <0.5x10^9/l Platelets <25x10^9/l	Wait until ANC ≥1.5 and platelets ≥75 give 75% dose or continue with GCSF.

Non-haematological

Palmar-plantar erythrodysethesia – week after prior pegylated liposomal doxorubicin dose

Current assessment	Week 4	Week 5	Week 6
Grade 1	Redose unless patient has experienced a previous grade 3 or 4 skin toxicity, in which case wait an additional week	Redose unless patient has experienced a previous grade 3 or 4 skin toxicity, in which case wait an additional week	Give 75% dose return to 4 week interval
Grade 2	Wait an additional week	Wait an additional week	Give 75% dose return to 4 week interval
Grade 3	Wait an additional week	Wait an additional week	Withdraw patient
Grade 4	Wait an additional week	Wait an additional week	Withdraw patient

Stomatitis week after prior pegylated liposomal doxorubicin dose

Current assessment	Week 4	Week 5	Week 6
Grade 1	Redose unless patient has experienced a previous grade 3 or 4 stomatitis toxicity, in which case wait an additional week	Redose unless patient has experienced a previous grade 3 or 4 stomatitis toxicity, in which case wait an additional week	Give 75% dose return to 4 week interval or withdraw patient per physician's assessment
Grade 2	Wait an additional week	Wait an additional week	Give 75% dose return to 4 week interval or withdraw patient per physician's assessment
Grade 3	Wait an additional week	Wait an additional week	Withdraw patient
Grade 4	Wait an additional week	Wait an additional week	Withdraw patient

Hepatic impairment

Bilirubin 20-50micromol/L	give 75% dose
Bilirubin >51micromol/L	give 50% dose

REFERENCES

1. SPC