LIPOSOMAL DOXORUBICIN (CAELYX)

A treatment option for women whose disease does not respond to, or whose disease relapses within twelve months from, initial platinum-based therapy.
NICE approved May 2005

Drug/Dosage:	Liposomal doxorubicin (Caelyx) 40mg/m^2 IV Day 1 The dose may be increased to 50mg/m^2 on subsequent cycles if well tolerated, and only with Consultant approval
Administration:	For doses < 90mg dilute in 250ml 5% Glucose For doses ≥ 90mg dilute in 500ml 5% Glucose Prior to infusion the giving set should be primed with 5% Glucose. Following administration, flush the line with 5% Glucose 100ml. To minimise the risk of infusion reactions, the initial dose is administered at a rate no greater than 1mg/minute. If no infusion reaction is observed, subsequent Caelyx infusions may be administered over 1 hour.
Frequency:	4 weekly cycle for 6 cycles Clinical review prior to each cycle
Main Toxicities:	myelosuppression; palmar/plantar erythema (PPE) (see Comments); stomatitis; infusion associated reactions (see Comments); cardiotoxicity (see Comments); alopecia (uncommon)
Anti-emetics:	moderately emetogenic
Extravasation:	non-vesicant
Regular Investigations:	FBC Day 1 U&Es Day 1 LFTs Day 1 CA 125 Day 1 MUGA Prior to starting, and during treatment (see Comments)
Comments:	Maximum cumulative dose = 450 – 550mg/m^2 Consider previous anthracycline exposure A baseline MUGA scan should be performed where the patient is considered at risk of having impaired cardiac function e.g. significant cardiac history, hypertension, obese, smoker, elderly, previous exposure to anthracyclines, previous thoracic radiotherapy. MUGA scan should be repeated if there is suspicion of cardiac toxicity at any point during treatment, or if cumulative anthracycline dose approaches maximum. **To minimise risk of PPE for the first 4 – 7 days after Caelyx infusion:** Keep hands & feet as cool as possible. Do not wear tight fitting gloves or socks, and avoid wearing tight-fitting footwear and high heeled shoes. Avoid exposing the skin to very hot water, such as the bath or washing up.

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Version: 3	Approved by Consultant: Dr S Essapen
Supersedes: Version 2	Date: 11.3.07
Prepared by: S Taylor	Checked by: S Punter

Do not rub the skin vigorously or use abrasive washcloths. Pat skin dry after washing
Avoid the use of topical anaesthetics as they can worsen skin reactions

For Infusion Associated Reactions (allergic-like or anaphylactoid-like reactions): Stop the infusion – usually symptoms resolve without further intervention. However, emergency supportive treatment should be available. In most patients, treatment can be resumed at a slower rate after all symptoms have been resolved, without recurrence. Infusion reactions rarely recur after the first treatment cycle.

Dose Modifications

Haematological Toxicity:

Neutrophil Count	Platelets	Dose Modification
> 1.5 x10^9/l	> 75 x10^9/l	Give 100% dose.
0.5 - 1.4 x10^9/l	25 - 75 x10^9/l	Wait until neutrophil count ≥ 1.5 x10^9/l & platelets ≥ 75 x10^9/l; then give 100% dose.
< 0.5 x 10^9/l	< 25 x10^9/l	Wait until neutrophil count ≥ 1.5 x10^9/l and platelets ≥ 75 x10^9/l; then give 75% dose

Hepatic Impairment:

Bilirubin (µmol/l)	Caelyx Dose
< 20	Give 100%
20 – 51	Give 50%
> 51	Give 25%

Cutaneous Toxicity (PPE and Stomatitis): Treat symptoms accordingly, and follow dosing guidelines below for future cycles. Pyridoxine can be used for Grade 1 or above PPE.

Toxicity Grade after prior Caelyx dose	Week 4 after prior Caelyx dose	Week 5 after prior Caelyx dose	Week 6 after prior Caelyx dose
Grade 1	Give full dose unless patient has experienced a previous Grade 3 or 4 toxicity, in which case wait an additional week	Give full dose unless patient has experienced a previous Grade 3 or 4 toxicity, in which case wait an additional week	Decrease dose by 25% and give 4 weekly or withdraw – clinical decision.
Grade 2	Wait an additional week	Wait an additional week	Decrease dose by 25% and give 4 weekly or withdraw – clinical decision
Grade 3	Wait an additional week	Wait an additional week	No further treatment
Grade 4	Wait an additional week	Wait an additional week	No further treatment

Reference: Gordon, AN et al; JCO (2001); 19 (14): 3312-3322