

Indication	For adjuvant or neo-adjuvant treatment of ER+ HER2- high risk early stage breast cancer or as an option for triple negative and / or BRCA positive EBC.
Treatment Intent	Adjuvant Neo-adjuvant
Frequency and number of cycles	4 cycles EC repeated every 14 days followed by 4 cycles accelerated paclitaxel repeated every 14 days.
Monitoring Parameters pre-treatment	<ul style="list-style-type: none"> • Virology screening: All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • Consider using actual BSA • ECG should be checked prior to cycle 1 and undertake ECHO/MUGA as clinically indicated. • Monitor FBC, LFT and U&E at each cycle. • If neuts <1 or PLT <100 delay 1 week and consider dose reduction. • Hepatic impairment: • EC: d/w consultant. • Paclitaxel: If bilirubin < 1.25 x ULN and transaminase < 10 x ULN, dose at full dose. Otherwise consider dose reduction, not recommended in severe hepatic impairment. • Renal impairment: • EC: d/w consultant • Paclitaxel: no dose reduction necessary. • Management of adverse reactions and dose adjustments: • Patients developing hypersensitivity reactions to paclitaxel may be rechallenged with full dose paclitaxel following prophylactic medication (e.g. famotidine 40mg po given 4 hours prior to treatment plus Hydrocortisone 100mg iv and chlorphenamine 10mg iv 30 minutes prior to treatment), then give paclitaxel over 3-6 hours (i.e. starting at over 6 hours and gradually increase rate if possible). • Dose reduce Paclitaxel by 20% in the event of >= grade 2 neuropathy and consider a delay until recovery to <= grade 1. • Consider omitting paclitaxel in event of recurrent >= grade 3 neuropathy or recurrent OR persistent >=grade 2 neuropathy following a dose reduction. • Dose reduction should be considered if any other grade 3 or 4 non-haematological toxicity or repeat appearance of grade 2 (except N&V and alopecia). Delay until resolution of toxicity to <= grade 1. • Common drug interactions: (for comprehensive list refer to BNF/SPC) Avoid concomitant use of paclitaxel with CYP2C8 or CYP3A4 inducers (e.g. rifampicin, carbamazepine, phenytoin) and inhibitors (e.g. ketoconazole erythromycin, fluoxetine, gemfibrozil, clopidogrel, cimetidine, ritonavir, nelfinavir). Caution, ciclosporin increases concentration of epirubicin.
References	KMCC protocol BRE-076 V2 (Changes to V2 made in line with SOP-005 for removal of ranitidine on KMCC protocols and on aria regimens). Breast NOG 02.05.2023

NB For funding information, refer to CDF and NICE Drugs Funding List

Protocol No	BRE-076	Kent and Medway SACT Protocol Disclaimer: No responsibility will be accepted for the accuracy of this information when used elsewhere.	
Version	V3	Written by	M.Archer
Supersedes version	V2	Checked by	C.Waters (V3) C.Wong (V1) V3 updated as per NOG agreement
Date	23.05.2023	Authorising consultant (usually NOG Chair)	R. Jyothirmayi (V1)

Cycle 1-4 Repeat every 14 days

Day	Drug	Dose	Route	Infusion Duration	Administration
1	Dexamethasone	8mg	PO		
	Ondansetron	<75yrs 16mg >=75yrs 8mg	IV	15 mins	In 50ml Sodium chloride 0.9%
	EPIRUBICIN	90mg/m²	IV	Slow bolus	Through the side of a fast running Sodium Chloride 0.9% intravenous infusion
	CYCLOPHOSPHAMIDE	600mg/m²	IV	Slow bolus	Through the side of a fast running Sodium Chloride 0.9% intravenous infusion
TTO	Drug	Dose		Directions	
	Dexamethasone	6mg	PO	OM for 3 days. Take with or just after food, or a meal.	
	Metoclopramide	10mg	PO	10mg up to 3 times a day as required. Do not take for more than 5 days continuously.	
	Ondansetron	8mg	PO	BD for 3 days	
	Filgrastim	300 mcg or consider dose of 480 mcg if patient > 80kg	SC	OD starting on day 3 for 5 days	

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Cycle 5-8 repeat every 14 days:

Day	Drug	Dose	Route	Infusion Duration	Administration
Day 1	Dexamethasone	12mg	IV	Bolus	
	Chlorphenamine	10mg	IV	Bolus	Over 3 min through a fast running Sodium chloride 0.9% intravenous infusion.
	Metoclopramide	20mg	IV	Bolus	
	Please ensure pre-meds are given 30 mins prior to paclitaxel				
	PACLITAXEL	175mg/m²	IV	3 hours	In 500ml Sodium Chloride 0.9% (non-PVC bag via a non-PVC giving set) via in-line 0.22 micron filter (if dose <150mg in 250ml Sodium chloride 0.9%). Flush with sodium chloride 0.9%.
TTO	Drug	Dose	Route	Directions	
	Dexamethasone	6mg	PO	OM for 3 days Take with or just after food, or a meal.	
	Metoclopramide	10mg	PO	10mg up to 3 times a day as required (max. 30mg per day including 20mg pre-chemo dose) Do not take for more than 5 days continuously.	
	Filgrastim	300 mcg or consider dose of 480 mcg if patient > 80kg	SC	OD starting on day 3 for 5 days	

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