LONDON CANCER ALLIANCE West and South

Breast Pathway Group – Vinorelbine IV 3 weekly cycle in Advanced Breast Cancer

Indication:	Second line or subsequent treatments of advanced breast cancer where anthracyclines have failed or are unsuitable. Patients with progressive breast cancer for whom combination chemotherapy or taxane therapy is deemed inappropriate
Regimen details:	In combination chemotherapy: Vinorelbine 25mg-30mg/m^2 (max 60mg) IV Day 1 & 8
Administration:	In 50ml Sodium Chloride 0.9% over 5-10 minutes, via fast running Sodium Chloride 0.9% infusion It is recommended to flush thoroughly with rapid free-flowing infusion of 250ml of Sodium Chloride 0.9% post infusion to minimise risk of post infusion pain
Frequency:	Day 1, every 21 days Objectively assess response after 3 cycles If responding, continue to a total of 6 cycles Occasionally treatment may be continued beyond 6 cycles, after consultant review
Pre-medication:	Not required
Anti- emetics:	Low emetogenicity Follow local anti-emetic policy
Supportive medication:	Mouthcare as per local policy
Extravasation:	Vesicant If there is any possibility that extravasation has occurred, contact a senior member of the medical team and follow local protocol for dealing with cytotoxic extravasation

Version: 1.0 Supersedes: all other versions	Approved by LCA Breast Pathway Chemotherapy Lead: Mark Harries November 2014
Reason for Update: LCA Protocol Development	Approved by LCA Joint Delivery Subgroup Co-Chairs: Pauline McCalla & Rebecca Johl
Prepared by: Isabel Munoz	Approved by LCA Medicines & Chemotherapy Steering Group Chair: Jamie Ferguson
Second check by: Lisa Yuen	Date prepared: November 2014 Review Date: November 2016

Regular investigations:

Prior to Cycle 1:

FBC	Day 1 (within 14 days)
LFTs	Day 1 (within 14 days)
U&Es	Day 1 (within 14 days)

Prior to Day 8 (all cycles):

FBC	Day 8 (within 48 hours)

Prior to Day 1 (all cycles):

FBC	Day 1 (within 48-72 hours)
LFTs	Day 1 (within 48-72 hours)
U&Es	Day 1 (within 48-72 hours)

Toxicities: Myelosupression, ovarian failure/infertility, peripheral neuropathy and neuropathy induced constipation, alopecia (usually mild), GI symptoms, myalgia, fatigue

DOSE MODIFICATIONS

Haematological Toxicity

Day 1:

Neutrophils (x 10^9/L)		Platelets (x 10^9/L)	Day 1 Dose
> 1.5	&	> 100	100% dose
< 1.5	&	< 100	Delay day 1 until recovered to above these levels then resume treatment. For second delay, consider 75% dose.

Day 8:

Neutrophils (x 10^9/L)		Platelets (x 10^9/L)	Day 8 Dose
> 1.5	&	> 100	100% dose
1.0 – 1.49	or	75 - 99	75% dose
< 1.0	&	< 75	Omit day 8 and consider dose reduction for next cycle

If significant myelotoxicity, or more than 2 delays, consider giving as a 4-weekly schedule on day 1 and day 15

Renal Impairment

Dose adjustment not required if CrCl ≥ 30ml/min.
If CrCl < 30ml/ml, discuss with consultant.

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Hepatic Impairment

If hepatic insufficiency is due to metastatic involvement, the liver function may recover in response to treatment. Therefore, for patients with massive liver metastases, i.e. > 75% of liver volume replaced by tumour, it is empirically suggested to reduce the dose of vinorelbine to 85% and monitor closely haematological toxicity.

If hepatic insufficiency is due to other reasons, use the table below:

Bilirubin		AST / ALT	Dose
< 1.5 x ULN	&	< 5 x ULN	100%
1.5 to 3 x ULN	&	< 5 x ULN	Postpone and reassess in 1 week, consider vinorelbine 50% dose. If toxicity persists for more than 3 weeks, discontinue treatment.
> 3 x ULN			Omit
		> 5 x ULN	Clinical decision, consider 33% dose reduction

Dose modifications for other toxicities as appropriate

	Vinorelbine dose
Grade 1 or 2 neurotoxicity	100% dose
Grade 3 or 5 neurotoxicity	Omit
Grade 3 mucositis	Give 75% dose
Grade 4 mucositis	Omit
Grade 3 or 4 constipation	Omit
Any other grade 3 toxicities	Give 75% dose
Any other grade 4 toxicities	Omit

Location of regimen delivery: Out-patient setting

Comments: None

Drug interactions: Aprepitant – increased vinorelbine plasma levels
Itraconazole – increased risk of neurotoxicity.
Omeprazole and fluoxetine may inhibit vinorelbine metabolism
Posazonazole and voriconazole- increased vinorelbine plasma levels

References: www.medicines.org.uk 0.8.2011
SELCN network protocols (PO Vinorelbine), accessed May 09

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SWSHCN Protocols. Vinorelbine. Revised Jan 09
NWLCN Breast Cancer protocols Oct 2012
UCLH – Dosage adjustment for Cytotoxics in Hepatic Impairment. January 2009
UCLH – Dosage adjustment for Cytotoxics in Renal Impairment. January 2009
LCA Breast Cancer Clinical Guidelines October 2013

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