

Breast Pathway Group – Vinorelbine IV weekly 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:	Monotherapy: Vinorelbine 25mg-30mg/m ² (max 60mg) IV weekly
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:	Weekly (max 18 weeks)
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
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)

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
<p>Disclaimer: The Joint Delivery Chemotherapy Nurse/Oncology Pharmacist Group is a sub-group of the Medicines & Chemotherapy Steering Group (MCSG) working within the London Cancer Alliance Integrated Cancer System (LCA). The output of the LCA MCSG includes documentation that can be adopted by healthcare organisations at their discretion. It is the responsibility of each individual organisation to ensure that appropriate governance and safety clearance procedures within their own clinical service have been followed prior to implementation of any such pieces of work. LCA assume no responsibility for this process within individual organisations, and no responsibility for the clinical management of individual patients or patient groups. Any clinical queries regarding individual patients or documentation should be directed to the relevant clinical team within the most appropriate healthcare organisation.</p> <p>©LCA Copyright 2014</p>		

Prior to Cycle 2 onwards:

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

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

DOSE MODIFICATIONS

Haematological Toxicity

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.

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.

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.

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
<p>Disclaimer: The Joint Delivery Chemotherapy Nurse/Oncology Pharmacist Group is a sub-group of the Medicines & Chemotherapy Steering Group (MCSG) working within the London Cancer Alliance Integrated Cancer System (LCA). The output of the LCA MCSG includes documentation that can be adopted by healthcare organisations at their discretion. It is the responsibility of each individual organisation to ensure that appropriate governance and safety clearance procedures within their own clinical service have been followed prior to implementation of any such pieces of work. LCA assume no responsibility for this process within individual organisations, and no responsibility for the clinical management of individual patients or patient groups. Any clinical queries regarding individual patients or documentation should be directed to the relevant clinical team within the most appropriate healthcare organisation.</p> <p>©LCA Copyright 2014</p>		

> 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
SELN network protocols (PO Vinorelbine), accessed May 09
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

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
<p>Disclaimer: The Joint Delivery Chemotherapy Nurse/Oncology Pharmacist Group is a sub-group of the Medicines & Chemotherapy Steering Group (MCSG) working within the London Cancer Alliance Integrated Cancer System (LCA). The output of the LCA MCSG includes documentation that can be adopted by healthcare organisations at their discretion. It is the responsibility of each individual organisation to ensure that appropriate governance and safety clearance procedures within their own clinical service have been followed prior to implementation of any such pieces of work. LCA assume no responsibility for this process within individual organisations, and no responsibility for the clinical management of individual patients or patient groups. Any clinical queries regarding individual patients or documentation should be directed to the relevant clinical team within the most appropriate healthcare organisation.</p> <p>©LCA Copyright 2014</p>		