Vinorelbine (breast)

Indication

Advanced breast cancer where initial treatment, including an anthracyclines, has failed or is inappropriate.

(NICE CG81)

ICD-10 codes

Codes pre-fixed with C50

Regimen details

Day	Drug	Dose	Route
1, 8 and 15	Vinorelbine*	30 mg/m² (max 60mg)	IV infusion

* start at 25mg/m² if patient is heavily pre-treated or has significant co-morbidities.

OR

Day	Drug	Dose	Route
1, 8 and 15	Vinorelbine	60 mg/m² (max 120 mg) or 80 mg/m² (max 160mg) *	PO

* After the first 3 administrations at 60 mg/m² doses may be escalated to 80 mg/m²

Cycle frequency

21 days

Number of cycles

Usually 6 cycles. Additional cycles may be given until disease progression, at consultants discretion.

Administration

Vinorelbine is administered in 50 mL sodium chloride 0.9% over 10 minutes, as per national guidance. Nurse to remain with patient throughout infusion.

Oral vinorelbine

Vinorelbine is available as 20mg, 30mg and 80mg capsules. The capsules should be swallowed whole with water and with or after food.

Equivalent doses:

IV vinorelbine	PO vinorelbine
30mg/m^2	80mg/m^2
25mg/m^2	60mg/m^2

Oral doses should be prescribed as per the table below:

BSA (m^2)	**Dose** (60mg/m^2)	**Dose** (80mg/m^2)
0.95-1.04	60mg	80mg
1.05-1.14	70mg	90mg
1.15-1.24	70mg	100mg
1.25-1.34	80mg	100mg
1.35-1.44	80mg	110mg
1.45-1.54	90mg	120mg
1.55-1.64	100mg	130mg
1.65-1.74	100mg	140mg
1.75-1.84	110mg	140mg
1.85-1.94	110mg	150mg
≥1.95	120mg	160mg

Pre-medication

Antiemetics as per local guidelines.

Emetogenicity

This regimen has moderate - low emetic potential (IV doses) or moderate-high (PO doses).

Additional supportive medication

H_2 antagonist or proton pump inhibitor if required.
Laxatives if required.
Mouthwashes as per local policy.

Extravasation

Vinorelbine (IV) – vesicant (Group 5)

Investigations – pre first cycle

Investigation	**Validity period** (or as per local practice)
FBC	14 days
U+E (including creatinine)	14 days
LFTs	14 days

Investigations - pre subsequent cycles

Investigation	**Validity period** (or as per local practice)
FBC	96 hours
U+E (including creatinine)	7 days
LFTs	7 days

In addition FBC is required within 24 hours of day 8 and 15.

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant

Investigation	**Limit**
Neutrophils	≥1.5 x 10^9/L
Platelets	≥100 x 10^9/L
Bilirubin	<1.5 x ULN
ALT/AST	<3 x ULN or < 5 x ULN in presence of liver metastases
Alkaline phosphatase	<2 x ULN

Dose modifications

- **Haematological toxicity**

Neutrophils (x 10^9/L)		**Platelets**(x 10^9/L)	**Vinorelbine dose**
≥1.5	and	≥100	100%
1.0-1.49	or	75-99	75%
<1.0	or	<75	Omit

- **Renal impairment**

No dose modifications necessary.

- **Hepatic impairment**

If bilirubin > 1.5-3 x ULN and/or AST/ALT > 5-20 x ULN delay vinorelbine for 7 days and recheck LFTs.
If toxicity persists beyond 3 weeks or bilirubin > 3 x ULN and/or AST/ALT > 20 x ULN discontinue treatment.

- **Other toxicities**

If grade 3-4 constipation omit vinorelbine and reduce dose to 75%. If second occurrence, omit and reduce dose to 50%.

If grade 3-4 neuropathy discontinue treatment.

Adverse effects - for full details consult product literature/ reference texts

- **Serious side effects**

Myelosuppression
Neurotoxicity
Infertility

- **Frequently occurring side effects**

Myelosuppression
Nausea and vomiting
Mucositis, stomatitis
Constipation
Peripheral neuropathy
Phlebitis

- **Other side effects**

Alopecia
Fatigue

Significant drug interactions – for full details consult product literature/ reference texts

Warfarin/coumarin anticoagulants: increased or fluctuating anticoagulant effects. Avoid if possible, consider switching patient to a low molecular weight heparin during treatment or if the patient continues taking an oral anticoagulant monitor the INR at least once a week and adjust dose accordingly.
CYP3A4 inducers (rifampicin, barbiturates): may reduce vinorelbine levels.
CYP3A4 inhibitors (ketoconazole, erythromycin): may increase vinorelbine levels.
Phenytoin: vinorelbine reduce absorption and efficacy of phenytoin, monitor levels and adjust dose as necessary.
Itraconazole: increased risk of neurotoxicity.

Additional comments

Nil

References

- National Institute of Health and Clinical Excellence Guideline CG81. Accessed 6 November 2014 via www.nice.org.uk
- Summary of Product Characteristics Vinorelbine (Pierre Fabre) accessed 6 November 2014 via www.medicines.org.uk

Written/reviewed by: Dr M Beresford (Consultant Oncologist, Royal United Hospital, Bath)

Checked by: Sarah Murdoch (Senior Oncology Pharmacist, SW Strategic Clinical Network)

Authorised by: Dr J Braybrooke (Consultant Oncologist, UHBristol NHS Trust, SW Strategic Clinical Network)

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