Vinorelbine Oral
Cumbria, Northumberland, Tyne & Wear Area Team

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Daily Dose</th>
<th>Route</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Vinorelbine</td>
<td>60 to 80 mg/m²</td>
<td>Oral</td>
<td>STAT DOSE</td>
</tr>
<tr>
<td>Day 8</td>
<td>Vinorelbine</td>
<td>60 to 80 mg/m²</td>
<td>Oral</td>
<td>STAT DOSE</td>
</tr>
<tr>
<td>Day 15*</td>
<td>Vinorelbine</td>
<td>60 to 80 mg/m²</td>
<td>Oral</td>
<td>STAT DOSE</td>
</tr>
</tbody>
</table>

DAY 15 is not given as part of lung cancer protocol.

ORAL VINORELBINE DOSAGE

Vinorelbine oral is available as 20mg and 30mg and 80mg capsules.

The following table gives the dose required for range of body surface area.

<table>
<thead>
<tr>
<th>Body Surface Area (BSA)</th>
<th>60 mg/m²</th>
<th>80 mg/m²</th>
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</thead>
<tbody>
<tr>
<td>BSA (m²)</td>
<td>Dose (mg)</td>
<td>Dose (mg)</td>
</tr>
<tr>
<td>1.25 to 1.34</td>
<td>80</td>
<td>100</td>
</tr>
<tr>
<td>1.35 to 1.44</td>
<td>80</td>
<td>110</td>
</tr>
<tr>
<td>1.45 to 1.54</td>
<td>90</td>
<td>120</td>
</tr>
<tr>
<td>1.55 to 1.64</td>
<td>100</td>
<td>130</td>
</tr>
<tr>
<td>1.65 to 1.74</td>
<td>100</td>
<td>140</td>
</tr>
<tr>
<td>1.75 to 1.84</td>
<td>110</td>
<td>140</td>
</tr>
<tr>
<td>1.85 to 1.94</td>
<td>110</td>
<td>150</td>
</tr>
<tr>
<td>≥1.95</td>
<td>120</td>
<td>160</td>
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</table>

Total dose must never exceed 160 mg per week. Even for patients with BSA ≥2 m².

Dose Escalation

The manufacturer recommends to escalate dose of oral vinorelbine from 60mg/m² after first three administrations to 80mg/m² except in those patients for whom the neutrophil count dropped once below 0.5 x 10⁹/l, or more than once between 0.5 and 1 x 10⁹/l during the first three administrations at 60mg/m².

CYCLE LENGTH AND NUMBER OF DAYS

BREAST CANCER: 21 day cycle, Day 1 & Day 8, Day 15.
LUNG CANCER: Every 21 days Day 1 & Day 8, omit day 15.

APPROVED INDICATIONS

As a single agent for breast cancer; and for Lung cancer
First-line therapy for NSCLC for patients that cannot receive platinum based therapy

PREMEDICATION

Ondansetron 8mg dose twice daily for one day, starting morning prior to treatment.
RECOMMENDED TAKE HOME MEDICATION
Metoclopramide 10 mg three times daily as required

INVESTIGATIONS / MONITORING REQUIRED
FBC, U&E, LFT prior to commencing (baseline radiology (CXR/ CT) for lung patients
- repeat radiology after 2 cycles)
FBC, U&E & LFT’s prior to each cycle

ASSESSMENT OF RESPONSE
Metastatic: Tumour size and patient symptomatic response

REVIEW BY CLINICIAN
To be reviewed by either a Nurse, Pharmacist or Clinician before every cycle.

NURSE / PHARMACIST LED REVIEW
On day 8 and or day 15 of each cycle

ADMINISTRATION NOTES
- Vinorelbine Oral has been demonstrated to bioequivalent to IV at doses tested:
  - Vinorelbine IV 25 mg/m² is equivalent to Vinorelbine oral 60 mg/m²
  - Vinorelbine IV 30 mg/m² is equivalent to Vinorelbine oral 80 mg/m²
- Food does not affect absorption but it is advised to take with food to reduce gastro-intestinal upset.
- Patient’s ability to drive or operate machinery may be affected however this is unlikely.
- The oral chemotherapy patient’s pathway is different to that of IV chemotherapy, responsibility for administering oral chemotherapy lies with the patient and their carer, the health care professional’s role is to support patients. See NECN Policy and ‘Oral Anticancer Medicines Handbook’.

TOXICITIES
- Rare anaphylaxis
- Severe venous irritation, discoloration and/or pain during injection
- Nausea & Vomiting
- Constipation
- Peripheral Neuropathy
- Fatigue, Myalgia
- Alopecia (Rare/mild)
- Myelosuppression (Neutropenia common)
The following counseling points should be discussed with the patient prior to them being issued with oral vinorelbine. (This can be a either a pharmacy or nursing role)

Missed dose: If the scheduled days dosing is missed, advise patient to not to take dose and contact their named chemotherapy contact. A blood count may be needed to confirm if taking the dose later is appropriate.

Post dose vomiting: In the case of vomiting within a few hours after drug intake, never repeat the administration of this dose.

Safe handling: Advice patient to contact their named chemotherapy contact if any of below happens;

• The liquid content of the capsules is an irritant and may cause damage if comes into contact with skin, mucosa or eyes.
• If capsule is chewed or sucked in error or is cut or damaged and contents touch skin, mouth or eyes, rinse affected area with water or preferably a normal saline solution.

Storage: Capsules should be refrigerated between 2 to 8°C

Disposal of unused medicine: Return to hospital pharmacy to be disposed of in a manner appropriate for disposal of dangerous substances.

Other Advice:

• Food does not affect absorption but it is advised to take with food to reduce gastro-intestinal upset.
• Patient’s ability to drive or operate machinery may be affected however this is unlikely.

DOSE MODIFICATION / TREATMENT DELAYS

Haematological Toxicity:

**Day One:**
Proceed if neutrophil count > 1.5, WBC > 3.0, plt >100, unless directed by an Oncology specialist.

Delay 1 week on DAY 1 if:-

<table>
<thead>
<tr>
<th>WCC</th>
<th>PLT</th>
<th>ANC</th>
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<tbody>
<tr>
<td>&lt; 3.0</td>
<td>&lt;100</td>
<td>&lt; 1.5</td>
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**Day Eight/Fifteen**
Proceed on if neutrophil count > 1.0, plt >100, unless directed by an Oncology specialist.

Omit treatment On DAY 8/15 if:-

<table>
<thead>
<tr>
<th>PLT</th>
<th>ANC</th>
<th>&lt; 1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 100</td>
<td>&lt; 1.0</td>
<td></td>
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</table>

**NB** On Day 8 of the cycle patients whose bloods are not at the required level will miss that dose and proceed to the next cycle of treatment as planned.
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- If WCC, Platelets or ANC still below required levels for treatment at after one week delay, delay treatment again and patient will need assessed and chemotherapy dose reduction by Oncologist
- If Hb < 10 & patient symptomatic will need blood transfusion, but may proceed with chemotherapy as planned if performance status (PS) stable.
- If pre-treatment (Day 1) U&E’s & LFT’s abnormal, delay treatment 1 week and discuss with Oncologist as may need dose reduction, On Day 8 Patient will miss that dose and proceed to next cycle of chemotherapy as planned.

Non- Haematological Toxicity:
If PS deteriorates to 3 or 4 and on assessment patient is more symptomatic withhold treatment and discuss with Oncologist

TREATMENT LOCATION
Can be given at Cancer Centre or Cancer Unit

REFERENCES:

Document Control

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<th>Document Title:</th>
<th>Vinorelbine oral CNTW protocol CRP09 L001</th>
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<td>Current Version:</td>
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<tr>
<td>Author:</td>
<td>Steve Williamson, Consultant Pharmacist</td>
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<tr>
<td>Approval Signature*:</td>
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<tr>
<td>Approved by:</td>
<td>Calum Polwart, Cancer Pharmacist NECN (provisional)</td>
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<tr>
<td>Date Approved:</td>
<td>29.05.14</td>
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<td>Due for Review:</td>
<td>May 2016</td>
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Summary of Changes

1.1 Reformatted from old NCN/CCA version and updated vinca guidance
1.2 Expiry date fixed
1.3 Added 80mg Capsules
1.4 Protocol reviewed and reissued, Antiemetic advice updated