

## **Breast metastatic vinORELBine (oral)**

ID: 1545 v.4 Endorsed

This protocol is based on limited evidence; refer to the evidence section of this protocol for more information.

Check for clinical trials in this patient group. Link to Australian Clinical Trials website

The anticancer drug(s) in this protocol <u>may</u> have been included in the ADDIKD guideline. Dose recommendations in kidney dysfunction have yet to be updated to align with the ADDIKD guideline. Recommendations will be updated once the individual protocol has been evaluated by the reference committee. For further information refer to the ADDIKD guideline. To assist with calculations, use the <u>eviQ Estimated Glomerular Filtration Rate (eGFR) calculator</u>.

International Consensus Guideline for Anticancer Drug Dosing in Kidney Dysfunction (ADDIKD)

Click here



2022

#### Related pages:

- Breast metastatic vinORELBine (IV)
- Breast metastatic trastuzumab three weekly and vinORELBine (oral)

## **Treatment schedule - Overview**

### **Cycle 1 and further cycles**

Drug	Dose	Route	Day
vinORELBine	60 mg/m <sup>2</sup> *	PO	1

<sup>\*</sup>If well tolerated, consider increasing the dose of vinorelbine to 80 mg/m² ONCE a week from week 4 (see dose escalation in **Dose modifications** section of the protocol)

Frequency: 7 days

Cycles: Continuous until disease progression or unacceptable toxicity

#### Notes:

- Bioequivalence: 60 mg/m² of oral vinorelbine is equivalent to 25 mg/m² of intravenous vinorelbine and 80 mg/m² of oral vinorelbine is equivalent to 30 mg/m² of intravenous vinorelbine.
- Two major differences are associated with oral administration: a higher inter-subject variability reflecting significant differences in the absorption rate from one patient to another, and a higher incidence of gastrointestinal side-effects. Oral administration seems to increase the incidence, but not the severity, of nausea, vomiting and diarrhoea. Prophylactic administration of anti-emetics is recommended.

**Drug status:** Vinorelbine oral capsules are PBS authority

Vinorelbine is available as 20 mg and 30 mg oral capsules

Cost: ~ \$430 per cycle

Treatment schedule - Detail

The supportive therapies (e.g. antiemetics, premedications, etc.), infusion times, diluents, volumes and routes of administration, if included, are listed as defaults. They may vary between institutions and can be substituted to reflect individual institutional policy.

Antiemetics if included in the treatment schedule are based upon recommendations from national and international guidelines. These are **defaults only** and may be substituted to reflect individual institutional policy. Select here for recommended doses of alternative antiemetics.

## **Cycle 1 and further cycles**

Day 1		
Granisetron	2 mg (P0)	60 minutes before chemotherapy
vinORELBine	60 mg/m <sup>2</sup> (PO)	ONCE a week with food. If well tolerated, consider increasing the dose to 80 mg/m² ONCE a week from week 4 (see dose escalation in Dose modifications section below)

Frequency: 7 days

**Cycles:** Continuous until disease progression or unacceptable toxicity

## Indications and patient population

• Advanced breast cancer as a single agent after failure of standard prior therapy, which includes an anthracycline.

## **Clinical information**

Caution with oral anti-cancer drugs	Select links for information on the safe prescribing, dispensing and administration of orally administered anti-cancer drugs.  Read more about the COSA guidelines and oral anti-cancer therapy
Emetogenicity moderate to high	Although this treatment is classified as having moderate to high emetogenicity, routine antiemetic premedication may not be required. Consider prophylaxis with a 5HT3 receptor antagonist e.g. granisetron 2 mg PO daily and re-assess routinely.
On atimation	Read more about preventing anti-cancer therapy induced nausea and vomiting
Constipation	Prescribe prophylactic laxatives to prevent constipation related to the use of vinca alkaloids.
Peripheral neuropathy	Assess prior to each treatment. If a patient experiences grade 2 or greater peripheral neuropathy, a dose reduction, delay, or omission of treatment may be required; review by medical officer before commencing treatment.
	Read more about peripheral neuropathy
	Link to chemotherapy-induced peripheral neuropathy screening tool
Pulmonary toxicity	There have been infrequent reports (less than 5% of patients) of pulmonary toxicity associated with vinorelbine.
	Read more about pulmonary toxicity associated with anti-cancer drugs.
Blood tests	FBC, EUC and LFTs at baseline and prior to each treatment.
Hepatitis B screening and prophylaxis	Routine screening for HBsAg and anti-HBc is NOT usually recommended for patients receiving this treatment.
	Read more about hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy
Vaccinations	Live vaccines are contraindicated in cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease.
	Refer to the recommended schedule of vaccination for immunocompromised patients, as outlined in the Australian Immunisation Handbook.
	Read more about COVID-19 vaccines and cancer.

## Fertility, pregnancy and lactation

Cancer treatment can have harmful effects on fertility and this should be discussed with all patients of reproductive potential prior to commencing treatment. There is a risk of foetal harm in pregnant women. A pregnancy test should be considered prior to initiating treatment in females of reproductive potential if sexually active. It is important that all patients of reproductive potential use effective contraception whilst on therapy and after treatment finishes. Effective contraception methods and adequate contraception timeframe should be discussed with all patients of reproductive potential. Possibility of infant risk should be discussed with breastfeeding patients.

Read more about the effect of cancer treatment on fertility

## Dose modifications

Evidence for dose modifications is limited, and the recommendations made on eviQ are intended as a guide only. They are generally conservative with an emphasis on safety. Any dose modification should be based on clinical judgement, and the individual patient's situation including but not limited to treatment intent (curative vs palliative), the anti-cancer regimen (single versus combination therapy versus chemotherapy versus immunotherapy), biology of the cancer (site, size, mutations, metastases), other treatment related side effects, additional co-morbidities, performance status and patient preferences. Suggested dose modifications are based on clinical trial findings, product information, published guidelines and reference committee consensus. The dose reduction applies to each individual dose and not to the total number of days or duration of treatment cycle unless stated otherwise. Non-haematological gradings are based on Common Terminology Criteria for Adverse Events (CTCAE) unless otherwise specified. Renal and hepatic dose modifications have been standardised where possible. For more information see dosing considerations & disclaimer.

The dose recommendations in kidney dysfunction (i.e. renal impairment) displayed may not reflect those in the ADDIKD guideline and have been included for historical reference only. Recommendations will be updated once the individual protocol has been evaluated by the reference committee, with this version of the protocol then being archived. Clinicians are expected to refer to the ADDIKD guideline prior to prescribing in kidney dysfunction.

International Consensus Guideline for Anticancer Drug Dosing in Kidney Dysfunction (ADDIKD).

Note: all dose reductions are calculated as a percentage of the starting dose

Dose Escalation	
For consideration only in the	Consider increasing the dose to 80 mg/m <sup>2</sup> weekly, <b>on week 4 if well tolerated</b>
absence of significant	<b>Note:</b> the dose should not be increased to 80 mg/m <sup>2</sup> in patients whose absolute
myelosuppression	neutrophil count has dropped once to less than $0.5 \times 10^9/L$ , or more than once between $0.5$ to $1.0 \times 10^9/L$ .

Haematological toxicity	
ANC x 10 <sup>9</sup> /L (pre-treatment blood t	est)
1.0 to less than 1.5	Refer to local institutional guidelines; it is the view of the expert clinicians that treatment should continue if patient is clinically well
0.5 to less than 1.0	Delay treatment until recovery
less than 0.5	Delay treatment until recovery and reduce vinorelbine by 25% for subsequent cycles
Febrile neutropenia or previous delay for myelosuppression	Delay treatment until recovery and reduce vinorelbine by 25% for subsequent cycles
Prolonged recovery greater than two weeks delay or 3 <sup>rd</sup> delay for myelosuppression	Delay treatment until recovery and reduce vinorelbine by 50% for subsequent cycles or cease
Platelets x 10 <sup>9</sup> /L (pre-treatment blo	pod test)
75 to less than 100	The general recommendation is to delay, however if the patient is clinically well it may be appropriate to continue treatment; refer to treating team and/or local institutional guidelines

Haematological toxicity	
50 to less than 75	Delay treatment until recovery
less than 50	Delay treatment until recovery and reduce vinorelbine by 25% for subsequent cycles

## Renal impairment

No dose modifications necessary

Hepatic impairment	
Hepatic dysfunction	
Mild	Reduce vinorelbine by 25%
Moderate	Reduce vinorelbine by 50%
Severe	Omit vinorelbine

Peripheral neuropathy	
Grade 2 which is present at the start of the next cycle	Reduce vinorelbine by 25%; If persistent, reduce vinorelbine by 50%
Grade 3 or Grade 4	Omit vinorelbine

## **Interactions**

Drug interactions in eviQ protocols are under review and being updated to align with current literature. Further site-wide updates and changes will occur in due course. References & Disclaimer

The drug interactions shown below are not an exhaustive list. For a more comprehensive list and for detailed information on specific drug interactions and clinical management, please refer to the specific drug product information and the following key resources:

- MIMS interactions tab (includes link to a CYP-450 table) (login required)
- Australian Medicines Handbook (AMH) interactions tab (login required)
- Micromedex Drug Interactions (login required)
- Cancer Drug Interactions
- Cytochrome P450 Drug Interactions

Vinorelbine		
	Interaction	Clinical management
CYP3A4 and P-gp inhibitors (e.g. amiodarone, aprepitant, azole-antifungals, ritonavir, lapatinib, nilotinib, sorafenib, macrolides, ciclosporin, grapefruit juice etc.)	Increased toxicity of vinorelbine possible due to reduced clearance	Monitor for vinorelbine toxicity (esp. neurotoxicity, myelosuppression)
CYP3A4 inducers (e.g. carbamazepine, phenytoin, phenobarbitone, rifampicin, St John's wort etc.)	Reduced efficacy of vinorelbine possible due to increased clearance	Monitor for decreased clinical response to vinorelbine
Mitomycin	Increased risk of pulmonary toxicity when vinorelbine administered following or concomitantly with mitomycin	Avoid combination or monitor closely for pulmonary toxicity (i.e. interstitial infiltrates, pleural effusion resulting in respiratory distress and cough)

General		
	Interaction	Clinical management
Warfarin	Anti-cancer drugs may alter the anticoagulant effect of warfarin.	Monitor INR regularly and adjust warfarin dosage as appropriate; consider alternative anticoagulant.
Direct oral anticoagulants (DOACs) e.g. apixaban, rivaroxaban, dabigatran	Interaction with both CYP3A4 and P-gp inhibitors /inducers.  DOAC and anti-cancer drug levels may both be altered, possibly leading to loss of efficacy or toxicity (i.e. increased bleeding).	Apixaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. If treating VTE, avoid use with strong CYP3A4 and P-gp inducers.  Rivaroxaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors.  Dabigatran: avoid combination with strong P-gp inducers and inhibitors.  If concurrent use is unavoidable, monitor closely for efficacy/toxicity of both drugs.
Digoxin	Anti-cancer drugs can damage the lining of the intestine; affecting the absorption of digoxin.	Monitor digoxin serum levels; adjust digoxin dosage as appropriate.
Antiepileptics	Both altered antiepileptic and anti- cancer drug levels may occur, possibly leading to loss of efficacy or toxicity.	Where concurrent use of an enzyme-inducing antiepileptic cannot be avoided, monitor antiepileptic serum levels for toxicity, as well as seizure frequency for efficacy; adjust dosage as appropriate. Also monitor closely for efficacy of the anti-cancer therapy.
Antiplatelet agents and NSAIDs	Increased risk of bleeding due to treatment related thrombocytopenia.	Avoid or minimise combination. If combination deemed essential, (e.g. low dose aspirin for ischaemic heart disease) monitor for signs of bleeding.
Serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs e.g. paroxetine) and serotonin noradrenaline reuptake inhibitors (SNRIs e.g. venlafaxine)	Increased risk of serotonin syndrome with concurrent use of 5-HT3 receptor antagonists (e.g. palonosetron, ondansetron, granisetron, tropisetron, dolasetron, etc.)	Avoid combination.  If combination is clinically warranted, monitor for signs and symptoms of serotonin syndrome (e.g. confusion, agitation, tachycardia, hyperreflexia).  For more information link to TGA Medicines Safety Update
Vaccines	Diminished response to vaccines and increased risk of infection with live vaccines.	Live vaccines (e.g. BCG, MMR, zoster and varicella) are contraindicated in patients on immunosuppressive therapy. Use with caution in patients on non-immunosuppressive therapy. For more information; refer to the recommended schedule of vaccination for cancer patients, as outlined in the Australian Immunisation Handbook

## **Administration**

eviQ provides safe and effective instructions on how to administer cancer treatments. However, eviQ does not provide every treatment delivery option, and is unable to provide a comprehensive list of cancer treatment agents and their required IV line giving set/filter. There may be alternative methods of treatment administration, and alternative supportive treatments that are also appropriate. Please refer to the individual

#### Day 1

#### This is an oral treatment

Safe handling and waste management

Safe administration

General patient assessment prior to each day of treatment.

Peripheral neuropathy assessment tool

Any toxicity grade 2 or greater may require dose reduction, delay or omission of treatment and review by medical officer before commencing treatment.

#### Pre treatment medication

Verify antiemetics taken or administer as prescribed.

## Ochemotherapy - Time out

#### Vinorelbine

- administer orally ONCE weekly
- · to be swallowed whole with a glass of water; do not break, crush or chew
- · to be taken at the same time every week with food
- . food does not affect absorption but it is advised patients take with a light snack to reduce G.I upset
- if the patient chews or sucks the capsule by mistake, they should rinse their mouth out with water or preferably sodium chloride 0.9%

Note: if a capsule is forgotten or vomited, consult treating team

Continue safe handling precautions until 7 days after completion of drug(s)

## **Discharge information**

Vinorelbine capsules

• Vinorelbine capsules with written instructions on how to take them.

#### **Antiemetics**

· Antiemetics as prescribed.

#### Laxatives

Ensure patient has prophylactic laxatives.

#### **Patient information**

· Ensure patient receives patient information sheet.

## Side effects

The side effects listed below are not a complete list of all possible side effects for this treatment. Side effects are categorised into the approximate onset of presentation and should only be used as a guide.

## Immediate (onset hours to days)

Nausea and vomiting

Read more about prevention of treatment induced nausea and vomiting

Early (onset days to weeks)	
Neutropenia	Abnormally low levels of neutrophils in the blood. This increases the risk of infection. Any fever or suspicion of infection should be investigated immediately and managed aggressively.  Read more about immediate management of neutropenic fever
Thrombocytopenia	A reduction in the normal levels of functional platelets, increasing the risk of abnormal bleeding.  Read more about thrombocytopenia
Oral mucositis	Erythematous and ulcerative lesions of the gastrointestinal tract (GIT). It commonly develops following chemotherapy, radiation therapy to the head, neck or oesophagus, and high dose chemotherapy followed by a blood and marrow transplant (BMT).  Read more about oral mucositis
Diarrhoea	Read more about treatment induced diarrhoea
	Read more about treatment induced diarmoea
Constipation	
Fatigue	Read more about fatigue
Arthralgia and myalgia	Generalised joint pain or and/or stiffness and muscle aches, often worse upon waking or after long periods of inactivity. Can improve with movement. May be mild or severe, intermittent or constant and accompanied by inflammation.  Read more about arthralgia and myalgia
Peripheral neuropathy	Typically symmetrical sensory neuropathy, affecting the fingers and toes, sometimes progressing to the hands and feet. It is associated with several classes of anti-cancer drugs. These include taxanes, platinum-based compounds, vinca alkaloids and some drugs used to treat multiple myeloma.  Read more about peripheral neuropathy
Late (onset weeks to months)	
	Apparemally law layels of rad blood calls (DDCs) or beamaglable in the blood
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood.

Late (onset weeks to months)	
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood.  Read more about anaemia
Alopecia - partial	Hair thinning and/or patchy hair loss. Patients can also experience mild to moderate discomfort of the hair follicles, and rarely pain as the hair is falling out.  Read more about alopecia
Pulmonary toxicity	Pulmonary toxicity may include damage to the lungs, airways, pleura and pulmonary circulation.  Read more about pulmonary toxicity associated with anti-cancer drugs

## **Evidence**

A search of the literature did not find strong evidence to support the use of oral vinorelbine in the treatment of advanced or metastatic breast cancer. A review of all current clinical trials evaluating the use of oral vinorelbine in metastatic breast cancer was published in Cancer Treatment Reviews in 2012.<sup>1</sup> A total of 31 studies, including more than 1000 patients were included in the overall analysis. Of these 31 studies, seven evaluated oral vinorelbine as monotherapy; whilst the remainder were in combination with capecitabine or trastuzumab predominantly but also with a range of other intravenous chemotherapies. The expert reference panel supported publication of the protocol on the basis of the information summarised below.

Oral vinorelbine has been used extensively for the treatment of non small cell lung cancer and has been shown to be preferred by patients over intravenous vinorelbine.<sup>2</sup>

Source	Study & Year Published	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
Phase II trials	Freyer et al. 2003 <sup>3</sup>	Yes	Yes	1 <sup>st</sup> line MBC
	Amadori et al. 2001 <sup>4</sup>	Yes	Yes	1 <sup>st</sup> line MBC

Source	Study & Year Published	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
	Blancas et al. 2010 <sup>5</sup>	Yes	Yes	1 <sup>st</sup> and 2 <sup>nd</sup> line MBC
	Mansour et al. 2010 <sup>6</sup>	Yes	No. 80 mg/m² d1, 8, q3w (after 1 cycle at 60 mg/m²)	1 <sup>st</sup> line MBC; post-anthracyclines +/- taxanes
	Addeo et al. 2009 <sup>7</sup>	Yes	No. 80 mg/m <sup>2</sup> weekly (fractionated at d1,3,5); 3 weeks on, 1 week off	1 <sup>st</sup> line MBC (elderly)
Observational studies	Bartsch et al. 2008 <sup>8</sup>	Yes	No. 60 mg/m <sup>2</sup> d1, 8, q3w	1st to 4th line MBC; post anthracyclines
	Palomo et al. 2012 <sup>9</sup>	Yes	No. Dosing regimen not clearly stated	1 <sup>st</sup> and 2 <sup>nd</sup> line MBC (+/- capecitabine)
Case series	-	-	-	-
Guidelines	Date published/revised	Supports Use	Is the dose and regimen consistent with the protocol?	Comments
NCCN	-	-	-	-
BCCA	-	-	-	-
ссо	-	-	-	-

## **Efficacy**

A summary of the evidence supporting the effect of this protocol is below. For more details on the individual studies, link here.

	Study	No. of patients	Control arm	Effect
Median overall survival	Freyer et al. 2003 <sup>5</sup>	64	-	24 months
Progression-free survival/median time to treatment progression	Addeo et al. 2009 <sup>7</sup>	32	-	7.1 months
Overall response rate	Addeo et al. 2009 <sup>7</sup>	32	-	41%

## **Toxicity**

A summary of the toxicities associated with this protocol are included in the table below. The most clinically significant toxicities for this treatment are myelosuppression and gastrointestinal toxicities.

Grade 3/4 toxicity	Study	Incidence of event (%)
Neutropenia	Freyer et al. 2003 <sup>3</sup> (n=64)	39.1
Leucopenia	Freyer et al. 2003 <sup>3</sup> (n=64)	28.1
Anaemia	Freyer et al. 2003 <sup>3</sup> (n=64)	6.3
Thrombocytopenia	Mansour et al. 2010 <sup>6</sup>	6.4

Grade 3/4 toxicity	Study	Incidence of event (%)
	(n=26)	
Infection	Mansour et al. 2010 <sup>6</sup> (n=26)	6.4
Nausea/Vomiting	Amadori et al. 2001 <sup>4</sup> (n=72)	31.8*
Diarrhoea	Amadori et al. 2001 <sup>4</sup> (n=72)	8.5
Constipation	Freyer et al. 2003 <sup>3</sup> (n=64)	1.6
Stomatitis	Freyer et al. 2003 <sup>3</sup> (n=64)	3.1
Neuropathy	Freyer et al. 2003 <sup>3</sup> (n=64)	1.6
Fatigue	Palomo et al. 2012 <sup>9</sup> (n=116)	3
Alopecia (Grade 2)	Palomo et al. 2012 <sup>9</sup> (n=116)	2

<sup>\*</sup> no primary prophylactic antiemetics administered

A quality of life questionnaire performed in the study by Freyer et al, revealed no significant alteration between baseline, week 8 and 16, in global quality of life.<sup>3</sup>

Caregivers described these oral regimens as convenient (81%), well tolerated (84%), and with good compliance by patients (76%).9

## References

- 1 Aapro, M. and J. Finek. 2012. "Oral vinorelbine in metastatic breast cancer: a review of current clinical trial results." Cancer Treat Rev 38(2):120-126.
- 2 Jensen, L. H., K. Osterlind and C. Rytter. 2008. "Randomized cross-over study of patient preference for oral or intravenous vinorelbine in combination with carboplatin in the treatment of advanced NSCLC." Lung Cancer 62(1):85-91.
- **3** Freyer, G., T. Delozier, M. Lichinister, et al. 2003. "Phase II study of oral vinorelbine in first-line advanced breast cancer chemotherapy." J Clin Oncol 21(1):35-40.
- 4 Amadori, D, P Koralewski, A Tekiela, et al. 2001. "Efficacy and safety of navelbine oral (NVBo) in first line metastatic breast cancer (MBC)." Eur J Cancer 37 (Suppl. 6) (abstract 713)
- 5 Blancas, I., S. Morales, N. Diaz, et al. 2010. "Efficacy and safety of oral vinorelbine (NVBO) in first-or second-line metastatic breast cancer (MBC)." J Clin Oncol; 28:15S (abstract 1090)
- 6 Mansour, M., and Haddad, N. 2010. "Phase II study of single agent oral vinorelbine as a first line chemotherapy for metastatic breast cancer patients previously treated with adjuvant anthracyclines and/or taxanes." Proc 21st International Congress on Anti-Cancer Treatment." (abstract 627)
- 7 Addeo, R., V. Faiola, G. Cennamo, et al. 2009. "A novel metronomic schedule of oral vinorelbine for the treatment of metastatic breast cancer in elderly patients: A phase II trial." J Clin Oncol 27:15 Suppl 1 (p 1085)
- 8 Bartsch. R, U. Pluschnig, C. Wenzel, et al. 2008. "Oral Vinorelbine in Metastatic Breast Cancer The Vienna Experience." Ann Oncol; 19 (Suppl. 8) (abstract 160)
- 9 Palomo, A. G., I. Glogowska, H. Sommer, et al. 2012. "Final results of an international retrospective observational study in

patients with advanced breast cancer treated with oral vinorelbine-based chemotherapy." Anticancer Res 32(10):4539-4545.

#### **Bibliography**

Trillet-Lenoir, V, H Sommer, T Delozier, et al. 2004. "Oral vinorelbine in metastatic breast cancer: Long-term results of 2 multicenter phase II studies." Eur J Cancer Supplements 2:3 (abstract 279)

## History

#### **Version 4**

Date	Summary of changes
09/05/2014	New protocol taken to Medical Oncology Reference Committee meeting.
31/05/2014	Approved and published on eviQ.
18/02/2016	Discussion with Medical Oncology Reference Committee Chairs and protocol to be reviewed every 5 years. Next review due in 3 years.
31/05/2017	Transferred to new eviQ website. Version number change to V.2.
	Hepatitis B screening changed to NOT recommended.
03/11/2017	<ul> <li>Protocol reviewed and the following changes were made:</li> <li>Notes regarding dose capping of vinorelbine removed, as it is the consensus of the eviQ reference committee that current practice is not to cap the dose at BSA 2.</li> <li>Antiemetic update - consensus of the reference committee that a 5HT3 antagonist is sufficient with oral vinorelbine. Dexamethasone not usually required unless regimen not tolerated. Dexamethasone removed from the detailed treatment schedule and antiemetics clinical information updated.</li> <li>Protocol version number increased to V.3. Review protocol in 2 years.</li> </ul>
10/05/2018	Haematological dose modifications updated as per consensus of the expert clinician group. Version number changed to V.4.
23/09/2019	Protocol reviewed at Medical Oncology Reference Committee meeting on 30/08/2019. No changes. Next review in 5 years.
21/06/2021	Changed antiemetic clinical information block to moderate to high, to align with new categories. See ID 7 Prevention of anti-cancer therapy induced nausea and vomiting (AINV) v5.

The information contained in this protocol is based on the highest level of available evidence and consensus of the eviQ reference committee regarding their views of currently accepted approaches to treatment. Any clinician (medical oncologist, haematologist, radiation oncologist, medical physicist, radiation therapist, pharmacist or nurse) seeking to apply or consult this protocol is expected to use independent clinical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use is subject to eviQ's disclaimer available at www.eviQ.org.au

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https://www.eviq.org.au/p/1545

08 Jun 2023

# Patient information - Breast cancer metastatic - Vinorelbine (oral)



Patient's name:

## Your treatment

The treatment schedule below explains how drug for this treatment is given.

Vinorelbine				
This treatment cycle is	repeated every 7 days. Your doctor w	ill advise you of the number of treatments you will have.		
Day	Treatment How it is given			
1	Vinorelbine (vi-NOR-el-been)	Take orally ONCE a week only, on the same day each week with food. Swallow whole with a glass of water, do not break, crush or chew. Rinse your mouth with water after swallowing the capsule.  The liquid content of the capsule is an irritant and may cause damage if in contact with skin, mucosa or eyes. Damaged capsules should not be swallowed. If you accidentally chew or suck the capsule you should rinse your mouth with water or salt water.  If you forget to take a dose or vomit the capsule(s), contact your doctor or nurse for advice.		

Vinorelbine capsules are available in two capsule strengths, 20 mg and 30 mg. It is important that you take the correct capsules and understand how to take them. Ask your doctor, nurse or pharmacist to complete the table below with the correct number of capsules for you:

Vinorelbine	Number of capsules
20 mg capsules	
30 mg capsules	

## When to get help

Anticancer drugs (drugs used to treat cancer) can sometimes cause serious problems. It is important to get medical help immediately if you become unwell.

IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you have any of the following at any time:	Emergency contact details  Ask your doctor or nurse from your treating team who to contact if you have a problem
<ul> <li>a temperature of 38°C or higher</li> <li>chills, sweats, shivers or shakes</li> <li>shortness of breath</li> <li>uncontrolled vomiting or diarrhoea</li> </ul>	Daytime:  Night/weekend:  Other instructions:

<ul> <li>pain, tingling or discomfort in your chest or arms</li> </ul>	
you become unwell.	

## Other information about your treatment

## Changes to your dose or treatment delays

Sometimes a treatment may be started at a lower dose or the dose needs to be changed during treatment. There may also be times when your treatment is delayed. This can happen if your doctor thinks you are likely to have severe side effects, if you get severe side effects, if your blood counts are affected and causing delays in treatment, or if you are finding it hard to cope with the treatment. This is called a dose reduction, dose change or treatment delay. Your doctor will explain if you need any changes or delays to your treatment and the reason why.

## **Blood tests and monitoring**

Anti-cancer drugs can reduce the number of blood cells in your body. You will need to have regular blood tests to check that your blood cell count has returned to normal. If your blood count is low, your treatment may be delayed until it has returned to normal. Your doctor or nurse will tell you when to have these blood tests.

### Other medications given during this treatment

- Anti-sickness (anti-nausea) medication: you may be given some anti-sickness medication. Make sure you take this
  medication as your doctor or nurse tells you, even if you don't feel sick. This can help to prevent the sickness starting.
- Laxatives: you may be given some medication to prevent or treat constipation. Your doctor or nurse will tell you how and when to take the laxatives.

## **Side effects**

Cancer treatments can cause damage to normal cells in your body, which can cause side effects. Everyone gets different side effects, and some people will have more problems than others.

The table below shows some of the side effects you may get with this treatment. You are unlikely to get all of those listed and you may also get some side effects that have not been listed.

Tell your doctor or nurse about any side effects that worry you. Follow the instructions below and those given to you by your doctor or nurse.

## Immediate (onset hours to days)

#### Nausea and vomiting

- You may feel sick (nausea) or be sick (vomit).
- Take your anti-sickness medication as directed even if you don't feel sick.
- Drink plenty of fluids (unless you are fluid restricted).
- Eat small meals more frequently.
- Try food that does not require much preparation.
- Try bland foods like dry biscuits or toast.
- Gentle exercise may help with nausea.
- Ask your doctor or nurse for eviQ patient information Nausea and vomiting during cancer treatment.
- Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have uncontrolled vomiting or feel dizzy or light-headed.

## Early (onset days to weeks)

#### Infection risk (neutropenia)

- This treatment lowers the amount of white blood cells in your body. The type of white blood
  cells that help to fight infection are called neutrophils. Having low level of neutrophils is
  called neutropenia. If you have neutropenia, you are at greater risk of getting an infection. It
  also means that your body can't fight infections as well as usual. This is a serious side effect,
  and can be life threatening.
- Wash your hands often.
- Keep a thermometer at home and take your temperature regularly, and if you feel unwell.
- Do your mouth care regularly.
- Inspect your central line site (if you have one) daily for any redness, pus or swelling.
- · Limit contact with people who are sick.
- Learn how to recognise the signs of infection.
- Ask your doctor or nurse for eviQ patient information Infection during cancer treatment.
- Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:
  - o a temperature of 38°C or higher
  - o chills, shivers, sweats or shakes
  - o a sore throat or cough
  - uncontrolled diarrhoea
  - shortness of breath
  - a fast heartbeat
  - become unwell even without a temperature.

# Low platelets (thrombocytopenia)

- This treatment lowers the amount of platelets in your blood. Platelets help your blood to clot. When they are low, you are at an increased risk of bleeding and bruising.
- Try not to bruise or cut yourself.
- · Avoid contact sport or vigorous exercise.
- Clear your nose by blowing gently.
- · Avoid constipation.
- Brush your teeth with a soft toothbrush.
- Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to.
- Tell your doctor or nurse if you have any bruising or bleeding.
- Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.

# Mouth pain and soreness (mucositis)

- You may have:
  - o bleeding gums
  - mouth ulcers
  - o a white coating on your tongue
  - o pain in the mouth or throat
  - · difficulty eating or swallowing.
- Avoid spicy, acidic or crunchy foods and very hot or cold food and drinks.
- · Try bland and soft foods.
- Brush your teeth gently with a soft toothbrush after each meal and at bedtime. If you normally floss continue to do so.
- Rinse your mouth after you eat and brush your teeth, using either:
  - o 1/4 teaspoon of salt in 1 cup of warm water, or
  - 1/4 teaspoon of bicarbonate of soda in 1 cup of warm water
- Ask your doctor or nurse for eviQ patient information Mouth problems during cancer treatment.
- Tell your doctor or nurse if you get any of the symptoms listed above.

## • You may get bowel motions (stools, poo) that are more frequent or more liquid. Diarrhoea • You may also get bloating, cramping or pain. • Take your antidiarrhoeal medication as directed by your doctor. Drink plenty of fluids (unless you are fluid restricted). · Eat and drink small amounts more often. • Avoid spicy foods, dairy products, high fibre foods, and coffee. Ask your doctor or nurse for eviQ patient information - Diarrhoea during cancer treatment. Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if your diarrhoea is not controlled, you have 4 or more loose bowel motions per day, and if you feel dizzy or light-headed. You may have bowel motions (stools, poo) that are less frequent, harder, smaller, painful or Constipation difficult to pass. • You may also get: o bloating, cramping or pain a loss of appetite nausea or vomiting. • Drink plenty of fluids (unless you are fluid restricted). • Eat plenty of fibre-containing foods such as fruit, vegetables and bran. Take laxatives as directed by your doctor. • Try some gentle exercise daily. • Tell your doctor or nurse if you have not opened your bowels for more than 3 days. • You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or Tiredness and lack of energy things you enjoy. (fatigue) • Do not drive or operate machinery if you are feeling tired. • Nap for short periods (only 1 hour at a time) • Prioritise your tasks to ensure the best use of your energy. • Eat a well balanced diet and drink plenty of fluids (unless you are fluid restricted). • Try some gentle exercise daily. Allow your friends and family to help. Tell your doctor or nurse if you get any of the symptoms listed above. • You may get muscle, joint or general body pain and stiffness. Joint and muscle pain and Applying a heat pack to affected areas may help. stiffness • Talk to your doctor or nurse about other ways to manage these symptoms. You may need medication to help with any pain. • You may notice a change in the sensations in your hands and feet, including: Nerve damage (peripheral tingling or pins and needles neuropathy) numbness or loss of feeling o pain. You may find it difficult to do everyday activities, such as doing up buttons or picking up small objects. • Test water temperature with your elbow when bathing to avoid burns. • Use rubber gloves, pot holders and oven mitts in the kitchen. • Wear rubber shoes or boots when working in the garden or garage. Keep rooms well lit and uncluttered. • Ask your doctor or nurse for eviQ patient information - Nerve problems during cancer treatment.

• Tell your doctor or nurse if you get any of the symptoms listed above.

Late (onset weeks to months)	
Low red blood cells (anaemia)	<ul> <li>You may feel dizzy, light-headed, tired and appear more pale than usual.</li> <li>Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion.</li> <li>Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have any chest pain, trouble breathing, or feel like your heart is racing.</li> </ul>
Hair thinning	<ul> <li>Your hair may become dry and may break easily.</li> <li>You may lose some of your hair.</li> <li>Use a gentle shampoo and a soft hairbrush.</li> <li>Take care with hair products like hairspray, hair dye, bleaches and perms.</li> <li>Protect your scalp from the cold with a hat or scarf.</li> <li>Protect your scalp from the sun with a hat and sunscreen of SPF 50 or higher.</li> <li>Ask your doctor or nurse about the Look Good Feel Better program (www.lgfb.org.au)</li> </ul>
Lung problems	<ul> <li>Lung problems are rare, but can be serious. They may occur throughout treatment or after the completion of treatment.</li> <li>You may get:         <ul> <li>shortness of breath</li> <li>fever</li> <li>dry cough</li> <li>wheezing</li> <li>fast heartbeat</li> <li>chest pain.</li> </ul> </li> <li>Your doctor will monitor how well your lungs are working during your treatment.</li> <li>Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have chest pain or become short of breath.</li> </ul>

## General advice for people having cancer treatment

## **Chemotherapy safety**

- Learn how to keep you and your family safe while you are having anticancer drugs.
- See our patient information sheet Chemotherapy safety at home.

#### **Blood clot risk**

- Cancer and anticancer drugs can increase the risk of a blood clot (thrombosis).
- Tell your doctor if you have a family history of blood clots.
- A blood clot can cause pain, redness, swelling in your arms or legs, shortness of breath or chest pain.
- If you have any of these symptoms go to your nearest hospital Emergency Department.

#### **Medications and vaccinations**

- Before you start treatment, tell your doctor about any medications you are taking, including vitamins or herbal supplements.
- Don't stop or start any medications during treatment without talking to your doctor and pharmacist first.
- Paracetamol is safe to take if you have a headache or other mild aches and pains. It is recommended that you avoid taking aspirin, ibuprofen and other anti-inflammatory type medications for pain while you are having treatment. However, if these medications have been prescribed by your doctor, do not stop taking them without speaking with your doctor.
- Vaccinations such as flu and tetanus vaccines are safe to receive while having treatment. Do not have any live vaccines during your treatment or for 6 months after it finishes. If you are unsure, check with your doctor before you have any vaccinations.
- People you live with should be fully vaccinated, including having live vaccines according to the current vaccination schedule. Extra
  care needs to be taken with hand washing and careful disposal of soiled nappies for infants who have recently received the
  rotavirus vaccine.

#### Other medical and dental treatment

- If you go to hospital or any other medical appointment (including dental appointments), always tell the person treating you that you are receiving anticancer drugs.
- Before you have any dental treatment, talk to your doctor.

#### Diet

- · While you are receiving this treatment it is important that you try to maintain a healthy diet.
- Grapefruit and grapefruit juice can interact with your medication and should be avoided while you are on this treatment.
- Speak to your doctor or nurse about whether drinking alcohol is safe with your treatment.
- If you have any concerns about recent weight loss or weight gain or questions about your diet, ask to speak to a dietitian.

## **Fertility**

- Some cancer treatments can reduce your fertility. This can make it difficult or impossible to get pregnant or father a child.
- Talk to your doctor or nurse before you start any treatment. Depending on your situation there may be fertility sparing options available to you and/or your partner, discuss these with your doctor or nurse.

#### Pregnancy and breastfeeding

- Some cancer treatments can be dangerous to unborn babies. Talk to your doctor or nurse if you think there is any chance that you could be pregnant.
- Do not try to get pregnant or father a child during this treatment. Contraception should be used during treatment and after stopping treatment. Ask your doctor or nurse about what type of contraception you should use.
- If you are planning pregnancy/fatherhood after completing this treatment, talk to your doctor. Some doctors advise waiting between 6 months and 2 years after treatment.
- · Do not breastfeed if you are on this treatment, as anti-cancer medications can also pass into breast milk.

## Sex life and sexuality

- The desire to have sex may decrease as a result of this treatment or its side effects.
- Your emotions and the way you feel about yourself may also be affected by this treatment.
- It may help to discuss your concerns with your partner and doctor or nurse.

#### **Quitting smoking**

- It is never too late to guit smoking. Quitting smoking is one of the best things you can do to help your treatment work better.
- · There are many effective tools to improve your chances of quitting.
- Talk to your treating team for more information and referral to a smoking cessation support service.

## Staying active

- · Research shows that exercise, no matter how small, has many benefits for people during and after cancer treatment.
- Talk to your doctor before starting an exercise program. Your doctor can advise whether you need a modified exercise program.

For more information about cancer treatment, side effects and side effect management see our Patient and carers section.

## Where to get more information

### Telephone support

• Call Cancer Council on 13 11 20 for cancer information and support.

## **Breast cancer information**

- Australasian Lymphology Association lymphoedema.org.au
- Australasian Menopause Society menopause.org.au
- Breast Cancer Network Australia bcna.org.au
- National Breast Cancer Foundation nbcf.org.au
- YWCA Encore breast cancer exercise program ywcaencore.org.au

## General cancer information and support

- Australian Rare Cancer (ARC) Portal arcportal.org.au/
- Beyondblue beyondblue.org.au
- Cancer Australia canceraustralia.gov.au
- Cancer Council Australia cancer.org.au
- Cancer Voices Australia cancervoicesaustralia.org

- CanTeen canteen.org.au
- Carers Australia carersaustralia.com.au
- CHILL Cancer related hair loss scalpcooling.org
- eviQ Cancer Treatments Online eviQ.org.au
- LGBTQI+ People and Cancer cancercouncil.com.au/cancer-information/lgbtqi
- Look Good Feel Better lgfb.org.au
- Patient Information patients.cancer.nsw.gov.au
- Radiation Oncology Targeting Cancer targetingcancer.com.au
- Redkite redkite.org.au
- Return Unwanted Medicines returnmed.com.au
- Staying active during cancer treatment patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/staying-active

## **Quit smoking information and support**

Quitting smoking is helpful even after you have been diagnosed with cancer. The following resources provide useful information and support to help you quit smoking. Talk to your treating team about any other questions you may have.

- Call Quitline on 13 QUIT (13 78 48)
- iCanQuit iCanQuit.com.au
- Patient Information patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/quitting-smoking
- Quitnow quitnow.gov.au

Additional notes:		

This document is a guide only and cannot cover every possible situation. The health professionals caring for you should always consider your individual situation when making decisions about your care. Contact your cancer clinic staff or doctor if you have any questions or concerns about your treatment, or you are having problems coping with side effects. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use of this document is subject to eviQ's disclaimer available at www.eviQ.org.au

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