

## Regimen Monograph

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## A - Regimen Name

## CRBPVINO Regimen

Vinorelbine-CARBOplatin

**Disease Site** Lung - Non-Small Cell

**Intent** Adjuvant

**Regimen Category** **Evidence-Informed :**

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

**Rationale and Uses** An alternative to cisplatin-vinorelbine as adjuvant treatment for completely resected stage II or IIIa non-small cell lung cancer

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**B - Drug Regimen**

<a href="#">vinorelbine</a>	25 mg /m <sup>2</sup>	IV	Days 1 and 8
<a href="#">CARBOplatin</a>	AUC 5	IV	Day 1

Adjust Carboplatin dose to AUC target (using Calvert formula) as outlined in "Other Notes" section.

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**C - Cycle Frequency****REPEAT EVERY 21 DAYS**

For 4 cycles (up to 6 for neoadjuvant) unless disease progression or unacceptable toxicity occurs

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**D - Premedication and Supportive Measures**

**Antiemetic Regimen:** Moderate + NK1 antagonist (Carboplatin AUC  $\geq$  5) (D1)  
Minimal (D8)

**Febrile Neutropenia Risk:** Low

**Other Supportive Care:**

Also refer to [CCO Antiemetic Summary](#)

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**E - Dose Modifications**

Doses should be modified according to the protocol by which the patient is being treated.

**Dosage with toxicity**

<b>Worst Toxicity / Counts in the Previous Cycle</b>	<b>Dosage for subsequent cycle</b>	
	<b>Carboplatin (% previous dose)</b>	<b>Vinorelbine (% previous dose)</b>
Febrile neutropenia, Thrombocytopenic bleeding, ANC < $0.5 \times 10^9/\text{L}$ for $\geq 5$ to 7 days and/or Grade 4 thrombocytopenia	75%*	75%*
Grade 2 or 3 peripheral neuropathy	n/a	Discontinue
Grade 3 non-hematologic toxicity	75%*	75%*
Grade 4 non-hematologic toxicity	Discontinue	Discontinue

\* Do not retreat until non-hematologic/ organ toxicity  $\leq$  grade 2, platelets  $\geq 100 \times 10^9/\text{L}$  and ANC  $\geq 1.5 \times 10^9/\text{L}$

**Dose on day 8 of cycle**

<b>Toxicity on day 8 of cycle</b>					
<b>Non-hematologic (related organ)</b>		<b>Hematologic</b>			<b>Day 8 Vinorelbine (% day 1 dose)</b>
		<b>ANC (<math>\times 10^9/\text{L}</math>)</b>		<b>Platelets (<math>\times 10^9/\text{L}</math>)</b>	
$\leq$ grade 2	and	$\geq 1.5$	and	$\geq 100$	100%
$\leq$ grade 2	and	1-1.49	and/or	75-99	50%
Grade 3 or 4 related organ	or	< 1	or	< 75	Omit

**Hepatic Impairment**

Total bilirubin	vinorelbine (% usual dose)
2-3 X ULN	50%
>3 X ULN	25%

No dosage adjustment required for carboplatin.

**Renal Impairment**

As creatinine clearance changes, adjust dosage of Carboplatin using the Calvert Formula . (See "Other Notes" section).

No adjustment needed for vinorelbine.

**Dosage in the Elderly**

No dosage adjustments are required for vinorelbine increased age. Caution should be exercised and dose reduction considered for carboplatin as elderly patients may have more severe myelosuppression and neuropathy.

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**F - Adverse Effects**

Refer to [vinorelbine](#), [CARBOplatin](#) drug monograph(s) for additional details of adverse effects

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
<ul style="list-style-type: none"> <li>• Myelosuppression +/- infection, bleeding (may be severe)</li> <li>• Nausea, vomiting</li> <li>• Fatigue</li> <li>• Constipation</li> <li>• Injection site reaction</li> <li>• Increased LFTs</li> <li>• Nephrotoxicity</li> <li>• Diarrhea</li> <li>• Neuropathy (may be severe)</li> <li>• Anorexia</li> <li>• Mucositis</li> </ul>	<ul style="list-style-type: none"> <li>• Hypersensitivity</li> <li>• Aterial thromboembolism</li> <li>• Venous thromboembolism</li> <li>• Hemolytic uremic syndrome</li> <li>• Pneumonitis</li> <li>• Radiation recall reaction</li> </ul>

- |   |  |
|---|--|
| <ul style="list-style-type: none"><li>• Hearing impaired</li><li>• Alopecia</li><li>• Abnormal electrolytes</li></ul> |  |
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## G - Interactions

Refer to [vinorelbine](#), [CARBOplatin](#) drug monograph(s) for additional details

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## H - Drug Administration and Special Precautions

Refer to [vinorelbine](#), [CARBOplatin](#) drug monograph(s) for additional details

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## I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

### Recommended Clinical Monitoring

- CBC; baseline and before each cycle. Interim counts should be done in first cycle and repeated if dose modifications necessary.
- Renal and liver function tests; baseline and before each cycle
- Clinical toxicity assessment (including neuropathy, ototoxicity, local toxicity, infection, bleeding); at each visit
- Grade toxicity using the current [NCI-CTCAE \(Common Terminology Criteria for Adverse Events\) version](#)

### Suggested Clinical Monitoring

- INR; Baseline and as clinically indicated

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## J - Administrative Information

Approximate Patient Visit	Day 1: 1.5 hours; Day 8: 0.5 hours
Pharmacy Workload (average time per visit)	22.018 minutes
Nursing Workload (average time per visit)	42.917 minutes

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## K - References

Carboplatin and vinorelbine drug monographs, Cancer Care Ontario.

Kenmotsu H, Ohde Y, Shukuya T, et al. Feasibility of postoperative adjuvant chemotherapy of cisplatin plus vinorelbine for completely resected non-small-cell lung cancer: a retrospective study in Japan. *Respir Investig*. 2012 Dec;50(4):157-61.

Kris MG, Gaspar LE, Chaft JE, et al. Adjuvant Systemic Therapy and Adjuvant Radiation Therapy for Stage I to IIIA Completely Resected Non-Small-Cell Lung Cancers: American Society of Clinical Oncology/Cancer Care Ontario Clinical Practice Guideline Update. *J Clin Oncol* 2017;35(25):2960-74.

Shukuya T, Takahashi T, Tamiya A, et al. Evaluation of the safety and compliance of 3-week cycles of vinorelbine on days 1 and 8 and cisplatin on day 1 as adjuvant chemotherapy in Japanese patients with completely resected pathological stage IB to IIIA non-small cell lung cancer: a retrospective study. *Jpn J Clin Oncol* 2009;39(3):158-62.

### **PEBC Advice Documents or Guidelines**

- [Adjuvant Systemic and Radiation Therapy for Stage I to IIIA Completely Resected Non-Small-Cell Lung Cancers: ASCO-CCO Clinical Practice Guideline Update](#)

**August 2021** Modified Rationale and Uses section

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## L - Other Notes

### Calvert Formula

**DOSE (mg) = target AUC X (GFR + 25)**

- AUC = product of serum concentration (mg/mL) and time (min)
- GFR (glomerular filtration rate) expressed as measured Creatinine Clearance or estimated from Serum Creatinine (by Cockcroft and Gault method or Jelliffe method)

(Calvert AH, Newell DR, Gumbrell LA, et al, Carboplatin dosage: Prospective evaluation of a simple formula based on renal function. J Clin Oncol, 1989; 7: 1748-1756)

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## M - Disclaimer

### **Regimen Abstracts**

*A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.*

*Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.*

### **Regimen Monographs**

*Refer to the [New Drug Funding Program](#) or [Ontario Public Drug Programs](#) websites for the most up-to-date public funding information.*

*The information set out in the drug monographs, regimen monographs, appendices and symptom management information (for health professionals) contained in the Drug Formulary (the "Formulary") is intended for healthcare providers and is to be used for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects of a particular drug, nor should it be construed to indicate that use of a particular drug is safe, appropriate or effective for a given condition. The information in the Formulary is not intended to constitute or be a substitute for medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*

*The format and content of the drug monographs, regimen monographs, appendices and symptom management*

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*information contained in the Formulary will change as they are reviewed and revised on a periodic basis. The date of last revision will be visible on each page of the monograph and regimen. Since standards of usage are constantly evolving, it is advised that the Formulary not be used as the sole source of information. It is strongly recommended that original references or product monograph be consulted prior to using a chemotherapy regimen for the first time.*

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