Regimen Monograph

A - Regimen Name

VINO Regimen

Vinorelbine

Disease Site	Gynecologic - Ovary
Intent	Palliative
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	For the treatment of recurrent advanced ovarian cancer.

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B - Drug Regimen

vinorelbine	25-30 mg /m²	IV	Days 1 and 8

Alternative Schedule:

vinorelbine	25-30 mg /m²	IV	Days 1, 8, 15

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C - Cycle Frequency

Standard schedule: REPEAT EVERY 21 DAYS

Alternative schedule: REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations have been adapted from clinical trials or product monographs and may be considered.

Dosage with toxicity

Worst toxicity in previous cycle	Dose (% previous dose)
Febrile neutropenia, thrombocytopenic bleeding, grade 4 neutropenia ≥ 7 days	75 % *
Delay for toxicity > 3 weeks	Discontinue
Moderate or severe neurotoxicity	Discontinue
Grade 3 related other organ/ non-hematological toxicity	75 % *
Grade 4 related other organ/ non-hematological toxicity	Discontinue
*Do not start new cycle until platelets ≥ 100 x 10^9/L, neutrophils ≥ 1.5 x 10^9/L, hemoglobin > 80g/L and major toxicity has recovered to ≤ grade 2 (may consider administering if neutrophils 1-1.5 x 10^9/L at 50% of planned dose).	

Hepatic Impairment

As vinorelbine undergoes hepatobiliary metabolism and excretion, administer with caution in hepatic insufficiency. Consider adjusting doses with hyperbilirubinemia.
Suggested adjustments for increases in total bilirubin:

Total Bilirubin (µmol/L)	% Usual dose
< 2 x ULN	100%
2-3 x ULN	50%
> 3 x ULN	25%

Renal Impairment

No adjustment required

Dosage in the Elderly

No dosage adjustments are required for increased age

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F - Adverse Effects

Refer to vinorelbine drug monograph(s) for additional details of adverse effects

Most Common Side Effects	Less Common Side Effects, but may be Severe or Life-Threatening
• Myelosuppression ± infection, bleeding (may be severe) • Nausea, vomiting, anorexia, stomatitis • Diarrhea • Alopecia • Vesicant • Neuropathy (sensory, motor,	• Pneumonitis • Radiation recall • SIADH • Arterial, venous thromboembolism • Hypersensitivity

autonomic) • Constipation (may be severe) • Fatigue • Pain (including tumour)	

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G - Interactions

Refer to vinorelbine drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to vinorelbine drug monograph(s) for additional details

Administration:

FOR INTRAVENOUS USE ONLY.

Intrathecal administration of other vinca alkaloids has resulted in death. Syringes containing this product should be labeled “WARNING – FOR INTRAVENOUS USE ONLY. FATAL if given intrathecally.”

- Mix in 50mL minibag (D5W, NS) to a final concentration 0.5 - 2mg/mL; infuse over 6-10 minutes through free-flowing IV.
- Or may push (at final concentration of 1.5 – 3mg/mL) through sidearm of free-flowing IV (D5W, NS); inject over 6-10 minutes.
- After administration is completed, the manufacturer recommends flushing IV line with at least 75 to 125mL of D5W or NS.
- Flushing the line before and after administration of vinorelbine may reduce injection site reactions and phlebitis risk.
- If diluted as above, the manufacturer states that vinorelbine (in PVC bags or polypropylene syringes) may be used for up to 24 hours at 5-30°C.
- Refrigerate unopened vials (2-8°C); protect from light and do not freeze.

Contraindications:

- Patients with known hypersensitivity to vinorelbine
- Patients who have drug-induced severe myelosuppression
- Intrathecal administration is absolutely contraindicated

Warnings/precautions:

- Use with extreme caution in patients with compromised marrow reserve
- May result in radiosensitizing effects with prior or concomitant radiation therapy
- Patients with pre-existing neuropathy or prior treatment with other neurotoxic drugs may have increased potential for neurotoxicity

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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 at each visit
- Liver function tests; Baseline and periodic
- Clinical toxicity assessment for signs of neurotoxicity, local toxicity, bleeding, infection, hypersensitivity, thromboembolism, lung or ototoxicity; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Local site toxicity ratings, if incidence of phlebitis; At each visit

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J - Administrative Information

Approximate Patient Visit	0.5 hour
Pharmacy Workload (average time per visit)	16.783 minutes
Nursing Workload (average time per visit)	36.667 minutes

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K - References

Bajetta E, Di Leo A, Biganzoli L, et al. Phase II study of vinorelbine in patients with pretreated advanced ovarian cancer: activity in platinum-resistant disease. J Clin Oncol 1996;14(9):2546-51.

Burger RA, DiSaia PJ, Roberts JA, et al. Phase II trial of vinorelbine in recurrent and progressive epithelial ovarian cancer. Gynecol Oncol 1999;72(2):148-53.

Sørensen P, Høyer M, Jakobsen A, et al. Phase II study of vinorelbine in the treatment of platinum-resistant ovarian carcinoma. Gynecol Oncol 2001;81(1):58-62.

Vinorelbine drug monograph, Cancer Care Ontario.

PEBC Advice Documents or Guidelines

- Systemic Therapy for Recurrent Epithelial Ovarian Cancer

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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.

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