Regimen Monograph

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A - Regimen Name

VNBL Regimen

VinBLAStine

Disease Site Hematologic - Lymphoma - Hodgkin

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 refractory Hodgkin's lymphoma

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vinBLAStine 6 mg/m² IV Day 1

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C - Cycle Frequency

REPEAT EVERY 7 TO 14 DAYS

Until disease progression, no evidence of further response, or unacceptable toxicity.

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

Other Supportive Care:

 Patients at risk of tumour lysis syndrome should have appropriate prophylaxis and be monitored closely.

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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

Suggested:

Worst Toxicity / Counts in Previous Cycle (x 10 ⁹ /L)	Dose (% previous dose)*
Febrile neutropenia, grade 4 ANC for ≥ 5-7 days or thrombocytopenic bleeding	75%*
Grade 3 related organ / non-hematologic	Hold, then 75%*
Grade 4 related organ / non-hematologic	Discontinue

^{*}Do not retreat until ANC \geq 1-1.5 x 10⁹L, platelets \geq 100 x 10⁹L and toxicity \leq grade 2

Hepatic Impairment

Bilirubin	% Usual dose
>1 - 2.5 x ULN	50%
> 2.5 x ULN	25%

Renal Impairment

No adjustment required.

Dosage in the Elderly

Toxicity may be increased; used with caution.

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F - Adverse Effects

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

More common (> 10%)	Less Common (1-10%)	<1% or unknown that are severe or life threatening
 Paresthesia Myelosuppression ± infection, bleeding Constipation (may be severe) Abdominal pain Anorexia Nausea, vomiting Dysgeusia Mucositis Alopecia (usually incomplete) 	 Hypertension Photosensitivity Rash Diarrhea Fatigue Phlebitis Hyperuricemia Musculoskeletal pain Depression Headache Seizure 	 Hypersensitivity SIADH Hearing impaired Autonomic/ cranial neuropathy, loss of deep tendon reflex

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G - Interactions

Refer to vinBLAStine drug monograph(s) for additional details

- Avoid concomitant use with CYP3A4 inhibitors.
- Avoid concomitant use with CYP3A4 substrates if possible. Monitor closely or consider dose adjustment if they must be used together.

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H - Drug Administration and Special Precautions

Refer to vinBLAStine drug monograph(s) for additional details

Administration

FOR INTRAVENOUS USE ONLY.

Intrathecal administration of other vinca alkaloids has resulted in death. Containers with this product should be labelled:

"WARNING – FOR INTRAVENOUS USE ONLY. FATAL if given intrathecally."

- Direct IV push is not recommended to reduce the risk of inadvertently administering vinca alkaloids via intrathecal route.
- Mix in 50 mL minibag (NS or D5W).
- Dilutions in large volumes (≥ 100mL) and infusions over ≥30-60 minutes are not recommended, since these can increase the risk of vein irritation and extravasation.
- If any signs or symptoms of extravasation occur, the injection or infusion should be immediately terminated and restarted in another vein. Any known or suspected extravasation should be managed promptly according to local guidelines.
- Store unopened vials at 2 to 8°C; protect from light.

Contraindications

- Patients who have hypersensitivity to vinblastine or its formulation
- Patients with severe myelosuppression or infection
- Intrathecal vinblastine administration is absolutely contraindicated.

Warnings/Precautions

- Myelosuppressive effects are more marked in patients with bone marrow infiltration, cachexia or skin ulcers
- Use with caution in hepatic impairment due to an increased risk of neurotoxicity.
- Use with caution in patients with ischemic heart disease and in combination with neurotoxic drugs.
- Do not give vinblastine more frequently than once every 7 days.
- Standard doses of vinblastine given for prolonged periods (e.g. daily for 7 days) may result in permanent or fatal neurologic toxicity and should not be used.

Pregnancy/lactation

- Vinblastine is contraindicated in pregnancy. Adequate contraception should be used by both sexes during vinblastine treatment and for at least 6 months after the last dose (general recommendation).
- Breast feeding is not recommended due to the potential secretion of vinblastine into breast milk
- Effects on fertility; Aspermia and amenorrhea have been reported. Recovery of menses is variable.

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- CBC; baseline and before each dose
- Liver function tests; baseline and as clinically indicated
- Clinical assessment for neurotoxicity, infection, bleeding, GI, local toxicity (ie. extravasation), hypersensitivity, hyperuricemia; at each visit
- Grade toxicity using the current <u>NCI-CTCAE</u> (Common Terminology Criteria for <u>Adverse Events</u>) version

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J - Administrative Information

Approximate Patient Visit 0.5 hour

Pharmacy Workload (average time per visit) 15.346 minutes

Nursing Workload (average time per visit) 35 minutes

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K - References

Kuruvilla J, Song K, Mollee P, et al. A phase II study of thalidomide and vinblastine for palliative patients with Hodgkin's lymphoma. Hematology 2006;11(1):25-9.

Little R, Wittes RE, Longo DL, et al. Vinblastine for recurrent Hodgkin's disease following autologous bone marrow transplant. J Clin Oncol 1998;16(2):584-8.

October 2020 Expanded into full regimen monograph

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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 <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> 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.

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