Regimen Monograph

A - Regimen Name

VINO Regimen
Vinorelbine

VINO+TRAS Regimen
Vinorelbine-Trastuzumab

Disease Site	Breast
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 metastatic breast cancer
Supplementary Public Funding	**trastuzumab** New Drug Funding Program (Trastuzumab (Biosimilar) in combination with Chemotherapy - Metastatic Breast Cancer) (NDFP Website)

trastuzumab
New Drug Funding Program (Trastuzumab (Biosimilar) - Second Line - Metastatic Breast Cancer) (NDFP Website)

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B - Drug Regimen

Note: Different trastuzumab products are **NOT INTERCHANGEABLE.**

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

For patients with HER2 positive tumours, trastuzumab may be given concurrently and then as a single agent.

trastuzumab	4 mg /kg	IV loading dose	Day 1, cycle 1 only

THEN,

trastuzumab	2 mg /kg	IV maintenance dose	Weekly (Q7 Days)

Alternative Schedule:

vinorelbine	25-30 mg /m²	IV	Days 1 and 8
trastuzumab	8 mg /kg	IV loading dose	Day 1, cycle 1 only

THEN,

trastuzumab	6 mg /kg	IV maintenance dose	Every 21 days

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C - Cycle Frequency

Standard schedule: REPEAT EVERY 28 DAYS

Alternative schedule: REPEAT EVERY 21 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.

See TRAS (Breast - Advanced) regimen for details on trastuzumab dose modifications.

Dosage with toxicity

Worst toxicity in previous cycle	Vinorelbine Dose (% previous dose)
Febrile neutropenia Thrombocytopenic bleeding ANC < 0.5 and/or grade 4 thrombocytopenia for ≥ 5 to 7 days	75 %*
Grade 2 peripheral neuropathy	Discontinue
Grade 3 peripheral neuropathy	Discontinue
Grade 3 related organ/ non-hematological toxicity	75 %*
Grade 4 related organ/ non-hematological toxicity, OR delay > 3 weeks	Discontinue

*Do not start new cycle until platelets ≥ 100 x 10^9/L, neutrophils ≥ 1.5 x 10^9/L, hemoglobin > 80 g/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).

Dose on Day 8, 15 of cycle

Toxicity on Day 8 (or 15) of cycle					**Vinorelbine**
Non–hematologic (related organ)		Hematologic			**Day 8 (or 15) (% day 1 dose)**
		ANC (x 10^9/L)		Platelets (x 10^9/L)	
≤ grade 2	and	≥ 1.5	and	≥ 100	100%
≤ grade 2	and	1-1.49	and/or	≥ 100	50%
Grade 3 or 4 related organ	or	< 1	or	<100	Omit

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 (micromol/L)	Vinorelbine (% Usual dose)
< 1.5 x ULN	100%
1.5 to 2 x ULN	50%
> 2 x ULN	25%

Renal Impairment

No dose adjustment required

Dosage in the Elderly

No dosage adjustments are required for increased age.

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F - Adverse Effects

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

See TRAS (Breast - Advanced) regimen for details on trastuzumab adverse effects.

Vinorelbine:

Very common (≥ 50%)	Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Nausea, vomiting • Myelosuppression +/- bleeding (may be severe)	• Constipation (may be severe) • Fatigue	• Alopecia • Anorexia • Diarrhea • Mucositis • Neuropathy (may be severe) • Injection site reaction	• Venous thromboembolism • ↑ LFTs • Hypersensitivity • Pneumonitis • SIADH • Radiation recall

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G - Interactions

Refer to vinorelbine (± trastuzumab) drug monograph(s) for additional details.

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H - Drug Administration and Special Precautions

Refer to vinorelbine (± trastuzumab) drug monograph(s) for additional details.

Note: Different trastuzumab products are **NOT INTERCHANGEABLE.**

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I - Recommended Clinical Monitoring

See TRAS (Breast - Advanced) regimen for details on trastuzumab monitoring.

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

Vinorelbine:

Recommended Clinical Monitoring

- CBC; Baseline and at each dose
- Liver function tests; Baseline and before each cycle
- Clinical toxicity assessment for signs of neurotoxicity, local toxicity, bleeding, infection, hypersensitivity, thromboembolism, lung or GI toxicity, radiation recall; 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

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J - Administrative Information

Approximate Patient Visit

VINO	0.5 hour
VINO+TRAS	First cycle: 2 hours; Subsequent cycles: 1 hour

Pharmacy Workload **(average time per visit)**

VINO	16.783 minutes
VINO+TRAS	21.328 minutes

Nursing Workload **(average time per visit)**

VINO	36.667 minutes
VINO+TRAS	49.167 minutes

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K - References

Jones S, Winer E, Vogel C, et al. Randomized comparison of vinorelbine and melphalan in anthracycline-refractory advanced breast cancer. J Clin Oncol 1995 Oct; 13(10): 2567-2574.

Zelek L, Barthier S, Riofrio M, et al. Weekly vinorelbine is an effective palliative regimen after failure with anthracyclines and taxanes in metastatic breast carcinoma. Cancer 2001; 92: 2267-72.

Keller AM, Mennel RG, Georgoulias VA, et al. Randomized Phase III Trial of Pegylated Liposomal Doxorubicin Versus Vinorelbine or Mitomycin C Plus Vinblastine in Women With Taxane-Refractory Advanced Breast Cancer. J Clin Oncol 2004; 22:3893-901.

Vinorelbine drug monograph, Cancer Care Ontario.

May 2024 Updated NDFP form

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M - Disclaimer

Regimen Abstracts

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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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