Regimen Monograph

A - Regimen Name

MTRXVINO Regimen

Methotrexate-Vinorelbine

Disease Site	Sarcoma - Desmoid Tumour
Intent	Curative
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	Chemotherapy treatment for aggressive fibromatosis in patients who do not tolerate vinblastine and methotrexate because of neurotoxicity.

back to top

B - Drug Regimen

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

back to top

Any use of the information is subject, at all times, to CCO's Terms and Conditions.

C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity.

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal

back to top

E - Dose Modifications

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

Dosage with toxicity

Hematologic Toxicities: See Appendix 6 for general recommendations.

If severe motor neurotoxicity: OMIT Vinorelbine.

Hepatic Impairment

Bilirubin	% of Usual Dose
1-2 X ULN	**REDUCE** Vinorelbine to 75% dose
2-3 X ULN	**REDUCE** Methotrexate to 50% dose
> 3 X ULN	**OMIT** Methotrexate
> 4 X ULN	**OMIT** Vinorelbine

Renal Impairment

Creatinine Clearance (mL/min)	% of Usual Dose*
61 to 80	**REDUCE** Methotrexate to 60% to 75% dose
50 to 60	**REDUCE** Methotrexate to 50% to 60% dose
< 50	**OMIT** Methotrexate

* dose reduction can be less conservative with methotrexate according to creatinine clearance in a low dose regimen.

Any use of the information is subject, at all times, to CCO's Terms and Conditions.

back to top

F - Adverse Effects

Refer to methotrexate, 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
• Nausea, vomiting • Fatigue • Constipation • Injection-site reaction • Diarrhea • Neuropathy (may be severe) • Anorexia • Mucositis • Alopecia • Increased LFTs • Myelosuppression +/- infection, bleeding	• Hypersensitivity • Arterial or venous thromboembolism • GI perforation • Pancreatitis • Pneumonitis • Tumour lysis syndrome • Nephrotoxicity • Leukoencephalopathy

back to top

G - Interactions

Refer to methotrexate, vinorelbine drug monograph(s) for additional details

back to top

H - Drug Administration and Special Precautions

Refer to methotrexate, vinorelbine drug monograph(s) for additional details

back to top

Any use of the information is subject, at all times, to CCO's Terms and Conditions.

I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Clinical toxicity assessment (including stomatitis and neurotoxicity); at each visit
- CBC; baseline and before each cycle
- Baseline and regular renal and hepatic function tests

- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

back to top

J - Administrative Information

Approximate Patient Visit	0.5 hour
Pharmacy Workload (average time per visit)	21.997 minutes
Nursing Workload (average time per visit)	41.667 minutes

back to top

K - References

Methotrexate and vinorelbine drug monographs, Cancer Care Ontario.

Weiss AJ, Horowitz S, Lackman RD. Therapy of desmoid tumours and fibromatosis using vinorelbine. Am J Clin Oncol (CCT) 1999; 22(2):193-5.

June 2019 Updated emetic risk category

back to top

Any use of the information is subject, at all times, to CCO's Terms and Conditions.

L - Other Notes

Sarcomas are rare tumours and as such benefit from referral to specialized centres where there will be access to multidisciplinary expertise including good radiology, orthopedic and thoracic surgery, medical oncology, radiation oncology, pathology, and other supportive care disciplines.

back to top

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 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.

Some Formulary documents, such as the medication information sheets, regimen information sheets and symptom management information (for patients), are intended for patients. Patients should always consult with their healthcare provider if they have questions regarding any information set out in the Formulary documents.

Any use of the information is subject, at all times, to CCO's Terms and Conditions.

While care has been taken in the preparation of the information contained in the Formulary, 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.

CCO and the Formulary's content providers shall have no liability, whether direct, indirect, consequential, contingent, special, or incidental, related to or arising from the information in the Formulary or its use thereof, whether based on breach of contract or tort (including negligence), and even if advised of the possibility thereof. Anyone using the information in the Formulary does so at his or her own risk, and by using such information, agrees to indemnify CCO and its content providers from any and all liability, loss, damages, costs and expenses (including legal fees and expenses) arising from such person's use of the information in the Formulary.

back to top