Regimen Monograph

A - Regimen Name

MTRXVNBL Regimen

Methotrexate-VinBLAStine

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	First line chemotherapy treatment for Aggressive Fibromatosis.

back to top

B - Drug Regimen

methotrexate	30 mg /m²	IV	Days 1, 8, 15 and 22
vinBLAStine	6 mg /m²	IV	Days 1, 8, 15 and 22

back to top

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. The following recommendations have been adapted from clinical trials or product monographs and may be considered.

Dosage with toxicity

Hematologic Toxicities: See Appendix 6 for general recommendations.
If severe motor neurotoxicity: **REDUCE** Vinblastine to 50% dose

Hepatic Impairment

Bilirubin	% of Usual Dose
1-2.5 X ULN	**REDUCE** Vinblastine to 50% dose
2-3 X ULN	**REDUCE** Methotrexate to 50% dose
> 2.5 X ULN	**REDUCE** Vinblastine to 25% dose
> 3 X ULN	**OMIT** Methotrexate

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.

back to top

F - Adverse Effects

Refer to methotrexate, vinBLAStine 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 • Increased LFTs • Abdominal pain • Alopecia • Constipation • Diarrhea • Mucositis • Myelosuppression +/- infection, bleeding • Neuropathy (may be severe) • Rash	• Hypersensitivity • Arterial or venous thromboembolism • GI perforation • Tumour lysis syndrome • Pancreatitis • Pneumonitis • Nephrotoxicity • Leukoencephalopathy

back to top

G - Interactions

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

back to top

H - Drug Administration and Special Precautions

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

back to top

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)	20.559 minutes
Nursing Workload (average time per visit)	46.667 minutes

back to top

K - References

Azzarelli A, Gronchi A, Bertulli R, et al. Low-dose chemotherapy with methotrexate and vinblastine for patients with advanced aggressive fibromatosis. Cancer 2001; 92: 1259-1264.

Methotrexate and vinblastine drug monographs, Cancer Care Ontario.

August 2019 Removed archived PEBC guideline link

back to top

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.

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back to top