Regimen Monograph

Regimen Name | Drug Regimen | Cycle Frequency | Premedication and Supportive Measures | Administrative Information | References | Other Notes | Disclaimer

A - Regimen Name

FCM+ALEM Regimen

Fludarabine-Cyclophosphamide-mitoXANTRONE-Alemtuzumab

Disease Site	Hematologic - Leukemia - Chronic Lymphocytic (CLL)
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. This **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). 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.
Rationale and Uses	For the treatment of T-cell prolymphocytic leukemia

back to top

B - Drug Regimen

mitoXANTRONE	8 mg /m²	IV	Day 1 ONLY
fludarabine	25 mg /m²	IV	Days 1 to 3
cyclophosphamide	200 mg /m²	IV	Days 1 to 3

Within 1 to 3 months after FCM completion, give:

Week 1:

alemtuzumab[a, b, c]	3 mg	IV / Subcut	(first dose)
alemtuzumab[a, b, c]	10 mg	IV / Subcut	(second dose)
alemtuzumab[a, b, c]	30 mg	IV / Subcut	(third dose)

(This drug is not publicly funded. Universal compassionate access program is available.)

Weeks 2 to 13:

alemtuzumab[a, b, c]	30 mg	IV / Subcut	3 times per week

(This drug is not publicly funded. Universal compassionate access program is available.)

a. Although not approved by Health Canada, alemtuzumab has been given subcutaneously instead of intravenously; the incidence of infusion reactions may be lower.

b. Gradual dose escalation is required at the initiation of therapy and after treatment interruptions of 7 days or more. In most patients, escalation to 30mg can be accomplished in 3-7 days. Initial doses can be administered in various ways; sequentially (daily on days 1 to 3) and on alternate days (i.e. days 1, 3, and 5). Both schedules were used in clinical trials.

c. Single doses of alemtuzumab greater than 30 mg or cumulative weekly doses of greater than 90 mg should not be administered since higher doses are associated with an increased incidence of pancytopenia.

back to top

C - Cycle Frequency

For **FCM: REPEAT EVERY 28 DAYS** for a usual total of 4 cycles unless disease progression or unacceptable toxicity.

In the clinical trial, **alemtuzumab** was given within 1 to 3 months of completion of FCM for a **SINGLE COURSE** (first week titration plus 12 weeks of maintenance).

back to top

D - Premedication and Supportive Measures

Antiemetic Regimen: Moderate (FCM)
Minimal (Alemtuzumab)

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

back to top

K - References

Hopfinger G, Busch R, Pflug N, et al. Sequential chemoimmunotherapy of fludarabine, mitoxantrone, and cyclophosphamide induction followed by alemtuzumab consolidation is effective in t-cell prolymphocytic leukemia. Cancer 2013;119:2258-67

June 2019 Updated emetic risk category

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.

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