

## Regimen Monograph

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## A - Regimen Name

## FU(IV-CIV)LCVR Regimen

Fluorouracil-Leucovorin (Modified De Gramont)

**Disease Site**      Gastrointestinal  
                                 Hepatobiliary / Liver / Bile Duct  
                                 Pancreas

**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.

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**B - Drug Regimen**

<a href="#">leucovorin</a>	400 mg /m <sup>2</sup>	IV over 2 hours	Day 1
<a href="#">fluorouracil</a> <i>THEN</i>	400 mg /m <sup>2</sup>	IV bolus, after leucovorin	Day 1
<a href="#">fluorouracil</a>	2400 mg /m <sup>2</sup>	IV continuous infusion over 46 hours (single dose)	Start on Day 1

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Until disease progression or unacceptable toxicity

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Approximate Patient Visit	3 hours
Pharmacy Workload (average time per visit)	24.292 minutes
Nursing Workload (average time per visit)	89.2 minutes

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Ciuleanu T, Diculescu M, Hoepffner NM, et al. A randomised phase II study of OSI-7904L versus 5-fluorouracil (FU)/leucovorin (LV) as first-line treatment in patients with advanced biliary cancers. Invest New Drugs 2007;25(4):385-90.

**Pancreas:**

Gill S, Ko YJ, Cripps C, et al. PANCREOX: A randomized phase III study of 5-fluorouracil/leucovorin with or without oxaliplatin for second-line advanced pancreatic cancer in patients who have received gemcitabine-based chemotherapy. J Clin Oncol. 2016 Sep 12 [Epub ahead of print]

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April 2023 Updated DPD deficiency and fluorouracil antidote information in the Other Notes section

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## L - Other Notes

### **DPD Deficiency Testing and Guidance**

Patients should be tested for DPD deficiency before starting treatment with fluorouracil. Refer to the [DPD Deficiency Guidance for Clinicians](#) for more information.

In patients with unrecognized DPD deficiency, acute, life-threatening toxicity may occur; if acute grade 2-4 toxicity develops, treatment should be stopped immediately and permanent discontinuation considered based on clinical assessment of the toxicities.

### **Antidote for Fluorouracil Overdose:**

**Uridine triacetate** is a prodrug of uridine and is a specific antidote for treating fluorouracil overdose or severe early onset toxicities. If available, consider administering as soon as possible (i.e. within 96 hours) for suspected overdose. If not available, treatment is symptomatic and supportive.

For usage approval and supply, contact Health Canada's [Special Access Program](#) (SAP) (Phone: 613-941-2108. On-call service is available for emergencies). Uridine triacetate (Vistogard®) is supplied by its manufacturer in the United States (Wellstat Therapeutics).

The recommended dosing and administration for **uridine triacetate** in patients  $\geq 18$  years is:

- 10 grams (1 packet of coated granules) orally every 6 hours for 20 doses in total, without regards to meals.
- Granules should not be chewed. They should be mixed with 3 to 4 ounces of soft foods such as applesauce, pudding or yogurt.
- The dose should be ingested within 30 minutes of preparation, followed by at least 4 ounces of water.
- Refer to the prescribing information on dose preparation for NG-tube or G-tube use.

Additional resources on the management of fluorouracil infusion overdose:

- [Management of Fluorouracil Infusion Overdose Guideline](#) (Alberta Health Services)
- [Management of Fluorouracil Infusion Overdose at the BCCA - Interim Guidance](#) (BC Cancer Agency)

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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.*

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### **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.*

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