

## Regimen Monograph

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## A - Regimen Name

# CISPFU+CETU Regimen

CISplatin-Fluorouracil-Cetuximab

**Disease Site**      Head and Neck

**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****Cycle 1:**

<a href="#">CISplatin</a>	100 mg /m <sup>2</sup>	IV	Day 1
<a href="#">fluorouracil</a>	1000 mg /m <sup>2</sup> /day	IV 24h continuous infusion	Daily, on days 1 to 4
<a href="#">cetuximab</a>	400 mg /m <sup>2</sup>	IV	Day 1 ONLY
<a href="#">cetuximab</a>	250 mg /m <sup>2</sup>	IV	Days 8, 15

(This drug is not currently publicly funded for this regimen and intent)

**Cycles 2 to 6:**

<a href="#">CISplatin</a>	100 mg /m <sup>2</sup>	IV	Day 1
<a href="#">fluorouracil</a>	1000 mg /m <sup>2</sup> /day	IV 24h continuous infusion	Daily, on days 1 to 4
<a href="#">cetuximab</a>	250 mg /m <sup>2</sup>	IV	Days 1, 8, 15

(This drug is not currently publicly funded for this regimen and intent)

**Note:** Report as regimen code CETU when used as maintenance after chemotherapy portion is complete

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**C - Cycle Frequency****REPEAT EVERY 21 DAYS**

For a maximum of 6 cycles of CISPFU+CETU until disease progression or unacceptable toxicity

After 6 cycles, patients with at least stable disease may continue to receive weekly maintenance cetuximab until disease progression or unacceptable toxicity.

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## D - Premedication and Supportive Measures

**Antiemetic Regimen:** High (D1)  
Minimal (D8, 15)

### Other Supportive Care:

Standard regimens for Cisplatin premedication and hydration should be followed. Refer to local guidelines.

Also refer to [CCO Antiemetic Recommendations](#).

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## J - Administrative Information

Pharmacy Workload (average time per visit) 31.647 minutes

Nursing Workload (average time per visit) 65.208 minutes

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## K - References

Vermorken JB, Mesia R, Rivera F, et al. Platinum-based chemotherapy plus cetuximab in head and neck cancer. *N Engl J Med*. 2008 Sep 11;359(11):1116-27.

Yoshino T, Hasegawa Y, Takahashi S, et al. Platinum-based chemotherapy plus cetuximab for the first-line treatment of Japanese patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck: results of a phase II trial. *Jpn J Clin Oncol*. 2013 May;43(5):524-31.

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

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## L - Other Notes

### DPD Deficiency

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,*

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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.

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