I'm ready to do what it takes

CYRAMZA: Dosing Recommendations for Combination and Monotherapy[1]

C
CYRAMZA
8 mg/kg IV infusion over 60 minutes (Days 1 and 15)*†

P
Paclitaxel
80 mg/m² IV infusion over ~60 minutes (Days 1, 8 and 15)

01 C P	02	03	04	05	06	07
08 P	09	10	11	12	13	14
15 C P	16	17	18	19	20	21
22	23	24	25	26	27	28

Premedication recommendations[1]

- Prior to each CYRAMZA infusion, premedicate all patients with an IV histamine H1 antagonist (e.g., diphenhydramine hydrochloride)
- For patients who have experienced a grade 1 or 2 infusion-related reaction (IRR), premedication must be given for all subsequent infusions
- For patients who experience a second grade 1 or 2 IRR administer dexamethasone (or equivalent), then, for subsequent infusions, premedicate with the following or equivalent medicinal products: an intravenous histamine H1 antagonist, paracetamol and dexamethasone

* Maximum of seven cycles (21 regimen).
† For IV infusion only. Do not administer as IV push or bolus. Continue CYRAMZA until disease progression or unacceptable toxicity. In the event of a grade 1 or 2 infusion-related reaction, reduce infusion rate by 50%. For the duration of the infusion and all subsequent infusions.
IV=intravenous.

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01 C P	02	03	04	05	06	07
08	09	10	11	12	13	14

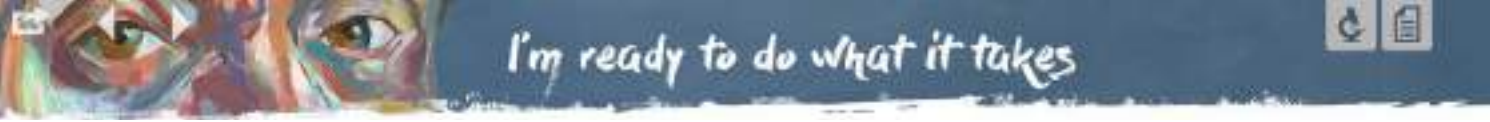
Premedication recommendations*

- Prior to each CYRAMZA infusion, premedicate all patients with an IV H1-antihistamine (e.g., diphenhydramine hydrochloride)
- For patients who have experienced a grade 1 or 2 infusion-related reaction (IRR), premedication must be given for all subsequent infusions
- For patients who experience a second grade 1 or 2 IRR administer dexamethasone (or equivalent); then, for subsequent infusions, premedicate with the following or equivalent medicinal products: an intravenous histamine H1-antagonist, paracetamol and dexamethasone

*Premedication recommendations.

Reference:

1. Ramucirumab (Cyramza) India Prescribing Information.



ABRIDGED PACK INSERT

Cyramza™ Ramucirumab Concentrate for Solution for Infusion 10mg/ml (100mg/10ml vial & 500mg/50 ml vial)

Indications: Cyramza™ (Ramucirumab) in combination with Paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy. Cyramza™ (Ramucirumab) monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with Paclitaxel is not appropriate. Cyramza™ (Ramucirumab), in combination with Docetaxel, is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy. CyramzaTM (Ramucirumab), in combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin and a fluoropyrimidine. **Dosage and administration:** Gastric cancer and gastro-oesophageal junction (GEJ) adenocarcinoma. Cyramza™ in combination with Paclitaxel: The recommended dose of Ramucirumab is 8 mg/kg on days 1 and 15 of a 28 day cycle, prior to Paclitaxel infusion. The recommended dose of Paclitaxel is 80 mg/m2 administered by intravenous infusion over approximately 60 minutes on days 1, 8 and 15 of a 28 day cycle (Please refer Paclitaxel pack insert). Cyramza™ as a single agent: The recommended dose of Ramucirumab as a single agent is 8 mg/kg every 2 weeks. Colorectal cancer: The recommended dose of Ramucirumab is 8 mg/kg every 2 weeks administered by intravenous infusion, prior to FOLFIRI administration. Prior to chemotherapy, patients should have a complete blood count Non-small cell lung cancer (NSCLC). The recommended dose of Ramucirumab is 10 mg/kg on day 1 of a 21 day cycle, prior to Docetaxel infusion. The recommended dose of Docetaxel is 75 mg/m2 administered by intravenous infusion over approximately 60 minutes on day 1 of a 21 day cycle (Please refer Docetaxel pack insert). **Method of administration:** After dilution, Cyramza™ is administered as an intravenous infusion over approximately 60 minutes. It should not be administered as an intravenous bolus or push. **Special warnings and precautions for use:** Arterial thromboembolic events; Gastrointestinal perforations; Severe bleeding; Pulmonary haemorrhage in NSCLC; Infusion-related reactions; Hypertension; Impaired wound healing; Hepatic impairment; Fistula; Proteinuria; Stomatitis; Renal impairment; Sodium restricted diet; Elderly patients with NSCLC. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients (L-Histidine, L-Histidine monohydrochloride, Glycine, Sodium chloride, Polysorbate 80). For patients with NSCLC, Ramucirumab is contraindicated where there is tumor cavitation or tumor involvement of major vessels. **Undesirable effects:** The most serious adverse reactions associated with Ramucirumab treatment (as a single agent or in combination with cytotoxic chemotherapy) were: Gastrointestinal perforation, Severe gastrointestinal haemorrhage, Arterial thromboembolic events. The most common adverse reactions observed in Ramucirumab-treated patients are: neutropenia, fatigue/asthenia, leukopenia, diarrhoea, epistaxis, and stomatitis. **Overdose:** There is no data on overdose in humans. Cyramza™ has been administered in a Phase 1 study up to 10 mg/kg every two weeks without reaching a maximum tolerated dose. In case of overdose, supportive therapy should be used.

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