

Continue treatment as long as there is evidence of a clinical response, usually a partial response or stable disease associated with symptom improvement (decreased pain, weight gain, improved performance status) or until there is unacceptable toxicity (also see Eligibility).

DOSE MODIFICATIONS:

1. Hematology – On Treatment Day

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
> 1.0	and	> 100	100%
0.5-1.0	or	50-100	75% or delay, based on clinical assessment
< 0.5	or	< 50	delay

2. Non – Hematologic Toxicities

Grade	Stomatitis	Diarrhea	Dose
1	Painless ulcers, erythema or mild soreness	Increase of 2-3 stools/day or mild increase in loose watery colostomy output	100%
2	Painful erythema, edema, or ulcers but can eat	Increase of 4-6 stools, or nocturnal stools or mild increase in loose watery colostomy output	Omit until toxicity resolved then resume at 100%
3	Painful erythema, edema, or ulcers and cannot eat	Increase of 7-9 stools/day or incontinence, malabsorption; or severe increase in loose watery colostomy output	Omit until toxicity resolved then resume at 75%
4	Mucosal necrosis, requires parenteral support	Increase of 10 or more stools/day or grossly bloody diarrhea, or grossly bloody colostomy output or loose watery colostomy output requiring parenteral I support; dehydration	Omit until toxicity resolved then resume at 50%.

- Doses reduced for toxicity should not be re-escalated.
- If doses must be omitted for Grade 2 toxicity twice in previous cycles, then commence next cycle at 75% dose when treatment is resumed.

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.

2. **Renal Dysfunction:** Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare). Use caution with pre-existing renal dysfunction.
3. **Pulmonary Toxicity:** Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.

Call the GI Systemic Therapy physician at your regional cancer centre or Dr. Lyly Le at (604) 930-2098 or 1-800-523-2885 with any problems or questions regarding this treatment program.

Date Activated: 01 January 1999

Date Revised: 1 Jul 2008 (gall bladder and cholangiocarcinoma added to indications, references added, contact physician revised)

References:

1. Burris HA 3rd, Moore MJ, Andersen J et al. Improvements in survival and clinical benefit with gemcitabine as first-line therapy for patients with advanced pancreas cancer: a randomized trial. *J Clin Oncol.* 1997 Jun;15(6):2403-13.
2. Dingle BH, Rumble RB, Brouwers MC et al. The role of gemcitabine in the treatment of cholangiocarcinoma and gallbladder cancer: a systematic review. *Can J Gastroenterol.* 2005 Dec;19(12):711-6