

BC Cancer Protocol Summary for Treatment of Relapsed/Progressing Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma Using Gemcitabine

Protocol Code
Tumour Group
Contact Physician

GOOVGEM
Gynecologic Oncology
GO Systemic Therapy

PREFACE:

- In platinum sensitive disease: patients should be considered for doublet therapy consisting of carboplatin plus either a taxane or gemcitabine or DOXOrubicin pegylated liposomal (e.g., GOOVCA^{TR}, GOOVCA^D, GOOVCA^G, GOOVPLDC)
- In platinum resistant disease (i.e., cancer progresses within six months of completing a platinum-containing treatment protocol): patients will ideally receive single agent carboplatin, as it is the least toxic and most convenient choice of the equally efficacious agents available (i.e., GOOVCA^{RB})
- In platinum refractory disease (i.e., cancer progresses while being treated with a platinum) choose between available agents based upon toxicity profile and convenience of dosing regimen. Options include: GOOVTO^P, GOOLDO^X, GOOVGEM, GOOVETO, GOOVVIN, GOOVTA^{X3}, GOOVDO^C.
- Patients who will not benefit from further therapy after second or subsequent rounds of chemotherapy can be identified by the following formula: “day 1 of treatment N to day of progression on treatment N+1 is less than or equal to 6 months.” They should be offered symptomatic management or investigational protocols.

ELIGIBILITY:

- Platinum refractory ovarian, primary peritoneal or Fallopian tube carcinoma
- Platinum resistant ovarian, primary peritoneal or Fallopian tube carcinoma in cases where patient-specific concerns dissuade the clinician from selecting single-agent carboplatin
- Platinum sensitive ovarian, primary peritoneal or Fallopian tube carcinoma in cases where actual or potential toxicity precludes the use of carboplatin or cisplatin alone or in combination with a taxane or gemcitabine.
- Adequate hematologic, liver and cardiac function
- PS ECOG 3 or better

TESTS:

- Baseline tests: CBC, & Diff
- Baseline, if clinically indicated: creatinine, ALT, total bilirubin, CA 125, CA 19-9, CA 15-3, CEA, SCC
- In Cycle 1 and in any Cycle in which a dose change has been made: Before treatment on days 1, 8, and 15: CBC & Diff
- In Cycle 2 and subsequent cycles when no dose change has been made: Before treatment on day 1 only: CBC & Diff
- If clinically indicated: creatinine, ALT, total bilirubin, CA 125, CA 19-9, CA 15-3, CEA, SCC

PREMEDICATIONS:

- Antiemetic protocol for chemotherapy with low to low-moderate emetogenicity (see SCNAUSEA)

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
gemcitabine	800 mg/m ² on day 1, 8, and 15	IV in 250 mL NS over 30 minutes

Repeat every 28 days until disease progression (usual treatment 9 cycles).

DOSE MODIFICATIONS:

- Hematology:** on day 1 in any cycle; and on day 1, 8 and 15 in cycle 1 and in all cycles in which a dose change has been made

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
Greater than or equal to 1.0	and	Greater than or equal to 100	100%
Less than 1.0	or	Less than 100	<i>If day 1:</i> delay until recovery, then proceed at reduced dose of 700 mg/m ² .
			<i>If day 8:</i> omit dose. If counts recover by day 15 proceed at reduced dose of 700 mg/m ² .
			<i>If day 15:</i> omit dose. Proceed at reduced dose of 700 mg/m ² with next cycle.

Note: If a recurrence of hematologic count problems occurs despite dose reduction to 700 mg/m²: either (i) discontinue gemcitabine if regimen had been day 1 and 8 only, or day 1 & 15 only; or, (ii) change to day 1 and 8 only, or day 1 and 15 only, if regimen had been day 1, 8 and 15.

- Febrile Neutropenia:** decrease subsequent doses to 700 mg/m². If a recurrence of febrile neutropenia occurs despite dose reduction to 700 mg/m²: either (i) discontinue gemcitabine if regimen had been day 1 and 8 only, or day 1 & 15 only; or, (ii) change to day 1 and 8 only, or day 1 and 15 only, if regimen had been day 1, 8 and 15.
- Pneumonitis:** discontinue gemcitabine if pneumonitis occurs
- Non-Hematologic Toxicities:** may include
 - Mucositis
 - Transient truncal rash
 - Fatigue
 - For Grade 3 toxicity, delay treatment until resolution of symptoms, then resume at 700 mg/m². If dose already reduced, switch to day 1 and 8 only or day 1 and 15 only. If Grade 3 toxicity persists, discontinue gemcitabine.
 - For Grade 4 toxicity, discontinue treatment.
 - Doses reduced for toxicity should not be re-escalated.

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.
4. **Fever and Flu-like Symptoms:** may commonly occur (fever 37%, flu-like symptoms 19%). Use acetaminophen as necessary for comfort.
5. **Drug Interaction – warfarin:** gemcitabine may cause increased anticoagulant effect of warfarin. Monitor INR carefully during and for 1 to 2 months after gemcitabine therapy; adjust warfarin dose as necessary.

Contact the GO Systemic Therapy physician at your regional cancer centre or GO Systemic Therapy Chair with any problems or questions regarding this treatment program.