

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

Protocol Code

GOOVVIN

Tumour Group

Gynecologic Oncology

Contact Physician

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^{DR}, 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, GOOVGE^M, GOOVETO, GOOVVIN, GOOVTA^{X3}, GOOVDO^C. If gemcitabine (GOOVGE^M), topotecan (GOOVTO^P) or DOXOrubicin pegylated liposomal (GOOVLD^{OX}) is used, only one of these options will be reimbursed in any one patient. Subsequently, if a patient is thought likely to benefit from one of the other two, a request should be submitted to the BC Cancer Compassionate Access Program (CAP).
- 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:

Patients must have:

- Platinum refractory ovarian, primary peritoneal or Fallopian tube carcinoma, **or**
- Platinum resistant ovarian, primary peritoneal or Fallopian tube carcinoma in cases where patient-specific concerns dissuade the clinician from selecting single-agent CARBOplatin, **or**
- 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.

Patients should have:

- Adequate hematologic, liver and cardiac function
- **Performance status** ECOG 3 or better

CAUTION:

- Hepatic dysfunction (see DOSE MODIFICATIONS, below)

TESTS:

- Baseline: CBC & Diff, total bilirubin, ALT
- Baseline, if clinically indicated: creatinine, sodium, potassium, CA 125, CA 19-9, CA 15-3, CEA, SCC
- Before each cycle (Day 1): CBC & Diff
- If clinically indicated: total bilirubin, ALT, creatinine, sodium, potassium, CA 125, CA 19-9, CA 15-3, CEA, SCC
- No labwork required prior to treatment on Day 8

PREMEDICATIONS:

- Antiemetic protocol for chemotherapy with rare to low emetogenicity (see SCNAUSEA).
- hydrocortisone 100mg IV prior to vinorelbine if patient experiences pain on administration.

TREATMENT:

| Drug | Dose | BC Cancer Administration Guideline |
|-------------|-----------------------------------------|---------------------------------------------------------------------------------------------------------------|
| vinorelbine | 25 mg/m ² on Day 1 and Day 8 | IV in 25 to 50 mL NS over 6 minutes, then flush line with 75 to 125 mL NS prior to removing/capping IV access |

Repeat every 21 days until disease progression (usual treatment 9 cycles).

DOSE MODIFICATIONS:

1. **Hematological:** prior to new cycle (Day 1)

| 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 | Delay until recovery; then give 100% and change interval to 28 days |

2. **Hepatic dysfunction:**

| Total bilirubin (micromol/L) | vinorelbine dose |
|------------------------------|------------------|
| Less than 35 | 100% |
| 36 to 50 | 50% |
| Greater than 50 | 25% |

3. **Non-Hematologic Toxicities:** may include

- Constipation
- Venous irritation: if severe, consider central venous access device (PICC or PORTACATH®)
- Hair thinning: total hair loss uncommon. Alopecia is a cumulative toxicity.
- Neuropathy: Mild to moderate peripheral neuropathy, usually reversible on discontinuation of therapy.

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Extravasation:** Vinorelbine causes pain and tissue necrosis if extravasated. It is recommended to flush thoroughly with 75 to 125 mL NS after infusing vinorelbine. Refer to BC Cancer Extravasation Guidelines.

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.