

ONCOGEM Injection (Gemcitabine)

Composition

ONCOGEM 200/1000/1.4 Injection

Each vial contains

Gemcitabine HCL equivalent to..... 200 mg/ 1 gm/ 1.4 gm

As sterile freeze dried powder for reconstitution

Indications

- Ovarian cancer in combination with carboplatin
- Breast cancer in combination with paclitaxel
- Non-small cell lung cancer in combination with cisplatin
- Pancreatic cancer as a single-agent
- Locally advanced or metastatic bladder cancer in combination with cisplatin

Dosage And Administration

Gemcitabine Injection is for intravenous use only.

- Ovarian cancer: 1000 mg/m₂ over 30 minutes on Days 1 and 8 of each 21-day cycle
- Breast cancer: 1250 mg/ m₂ over 30 minutes on Days 1 and 8 of each 21-day cycle
- Non-small cell lung cancer: 4-week schedule, 1000 mg/ m₂ over 30 minutes on Days 1, 8, and 15 of each 28-day cycle: 3-week schedule; 1250 mg/ m₂ over 30 minutes on Days 1 and 8 of each 21-day cycle
- Pancreatic cancer: 1000 mg/ m₂ over 30 minutes once weekly for up to 7 weeks (or until toxicity necessitates reducing or holding a dose), followed by a week of rest from treatment. Subsequent cycles should consist of infusions once weekly for 3 consecutive weeks out of every 4 weeks
- Bladder cancer- 1000 mg/ m₂ should be given on Days 1, 8 and 15 of each 28-day cycle in combination with cisplatin
- Dose Reductions or discontinuation may be needed based on toxicities

Contraindications

- Hypersensitivity to gemcitabine or to any of the excipients
- Breast-feeding

Most Common Adverse Reactions

Nausea and vomiting, anaemia, aspartate aminotransferase (AST), alanine aminotransferase (ALT), neutropenia, leukopenia, alkaline phosphatase, proteinuria, fever, hematuria, rash, thrombocytopenia, dyspnea

Storage

Store in a cool dry place. Do not refrigerate.

Packaging Information

ONCOGEM 200 Injection: vial of 10 ml

ONCOGEM 1000 Injection: vial of 50 ml

ONCOGEM 1.4 Injection: vial of 50 ml

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