Gemtor® IV Injection

Gemcitabine USP Injection

DESCRIPTION

Gemtor® IV Injection is a preparation of Gemcitabine. Gemcitabine kills cells undergoing DNA synthesis and blocks the progression of cells through the G1/S-phase boundary. Gemcitabine is metabolized by nucleoside kinases to diphosphate (dFdCDP) and triphosphate (dFdCTP) nucleosides. Gemcitabine diphosphate inhibits ribonucleotide reductase, an enzyme responsible for catalyzing the reactions that generate deoxynucleoside triphosphates for DNA synthesis, resulting in reductions in deoxynucleotide concentrations, including dCTP. Gemcitabine triphosphate competes with dCTP for incorporation into DNA. The reduction in the intracellular concentration of dCTP by the action of the diphosphate enhances the incorporation of gemcitabine triphosphate into DNA (self-potentiation). After the gemcitabine nucleotide is incorporated into DNA, only one additional nucleotide is added to the growing DNA strands, which eventually results in the initiation of apoptotic cell death.

INDICATIONS

- In combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.
- In combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.
- In combination with cisplatin for the treatment of non-small cell lung cancer
- As a single agent for the treatment of pancreatic cancer.

DOSAGE AND ADMINISTRATION

- **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 21day cycle.
- **Non-Small Cell Lung Cancer:** 1000 mg/m2 over 30 minutes on Days 1, 8, and 15 of each 28-day cycle or 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 the first 7 weeks, then one week rest, then once weekly for 3 weeks of each 28-day cycle.

CONTRAINDICATIONS

Hypersensitivity

SIDE EFFECTS

- Nausea/vomiting
- Anemia, neutropenia, thrombocytopenia
- Hepatic transaminitis
- Increased alkaline phosphatase, proteinuria, hematuria
- Fever
- Rash
- Dyspnea
- Peripheral edema

WARNING AND PRECAUTION

Schedule-dependent toxicity: Increased toxicity with infusion time greater than 60 minutes or dosing more frequently than once weekly. Myelosuppression: Monitor for myelosuppression prior to each cycle and reduce or withhold dose for severe myelosuppression. Pulmonary Toxicity and Respiratory Failure: Discontinue Gemcitabine immediately for unexplained new or worsening dyspnea or evidence of severe pulmonary toxicity. Hemolytic-Uremic Syndrome (HUS): Monitor renal function prior to initiation and during therapy. Discontinue Gemcitabine for HUS or severe renal impairment.

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. Gemcitabine can cause fetal harm when administered to a pregnant woman. Based on its mechanism of action, Gemcitabine is expected to result in adverse reproductive effects. Gemcitabine was teratogenic, embryotoxic, and fetotoxic in mice and rabbits. If Gemcitabine is used during pregnancy, or if the patient becomes pregnant while taking Gemcitabine, the patient should be apprised of the potential hazard to a fetus.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Gemcitabine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PHARMACEUTICAL PRECAUTION

Store below 30 °C temperature, away from light & wet place. Keep out of reach of children.

PACKAGING

Gemtor® 200 IV Injection : Each box contains 1 vial of Gemcitabine USP 200 mg injection.

Gemtor® 1g IV Injection : Each box contains 1 vial of Gemcitabine USP 1 gm injection.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
® REGD. TRADEMARK
R/PM0540 V01