GEMCITABINE FOR INJECTION v/s GEMCITABINE INJECTION

Particulars	Gemcitabine for Injection	Gemcitabine Injection
FDA Approval/Path	ANDA-505(j)	NDA-505(b)(2)
Dosage Form	Lyophilized Powder for Reconstitution	Solution for Injection
Active Ingredient	Gemcitabine Hydrochloride	Gemcitabine Hydrochloride
Strengths	200 mg/vial, 1 g/vial and 2 g/vial	100 mg/mL
Route of Administration	For Intravenous Use Only	For Intravenous Use Only
Clinical Presentations	200 mg/vial 1 g/vial 2 g/vial	2 mL vial [200 mg / 2 mL] 10 mL vial [1 g / 10 mL] 15 mL vial [1.5 g / 15 mL] 20 mL vial [2 g / 20 mL]
Package Term/Container	Sterile; Single Use Vials	Sterile; Multiple Dose Vials
Condition of Use	Indicated in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy. Indicated 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. Indicated in combination with cisplatin for the treatment of non-small cell lung cancer. Indicated as a single agent for the treatment of pancreatic cancer.	Indicated in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy. Indicated 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. Indicated in combination with cisplatin for the treatment of non-small cell lung cancer. Indicated as a single agent for the treatment of pancreatic cancer.
Reconstitution	Reconstituted with 0.9% sodium chloride solution [i.e. Yield 38 mg/mL Concentration] followed by dilution with 0.9% sodium chloride solution for intravenous infusion. Final concentrations may be as low as 0.1 mg/mL.	Diluted with 0.9% sodium chloride to concentrations as low as 0.1 mg/mL for intravenous infusion.
Storage	Prior to and after reconstitution, store at controlled room temperature 20°C to 25°C (68°F to 77°F) [See USP] Administer solution within 24 hours. Discard unused portion.	Store at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature]. Discard 28 days after initial puncture.