Gemcitabine for Injection is for intravenous use only. It is not recommended for intramuscular or subcutaneous injection.

**INDICATIONS AND USAGE**

Gemcitabine for Injection is indicated as a single agent (1.4) for the treatment of patients with non-small cell lung cancer (14.1) and pancreatic cancer (14.3) and in combination with paclitaxel for the first-line treatment of patients with locally advanced or metastatic breast cancer (14.2).

**CONTRAINDICATIONS**

Gemcitabine for Injection is contraindicated for patients who are hypersensitive to any excipients or components of the product.

**WARNINGs AND PRECAUTIONS**

Gemcitabine for Injection is associated with an increased risk of myelosuppression (3.2) and gastrointestinal toxicity (3.3). Patients should be monitored for these toxicities prior to each dose.

**ADVERSE REACTIONS**

The most common adverse reactions (incidence ≥25%) associated with Gemcitabine for Injection therapy are neutropenia, thrombocytopenia, and anemia. Other adverse reactions include nausea, vomiting, diarrhea, stomatitis, fatigue, dyspnea, rash, fever, and infections.

**DRUG INTERACTIONS**

Gemcitabine for Injection is not associated with any known drug interactions. However, patients taking Gemcitabine for Injection should be monitored for any potential interactions.

**DOSE AND ADMINISTRATION**

Gemcitabine for Injection should be administered intravenously at a dose of 1000 mg/m² over 30 minutes on Days 1 and 8 of each 21-day cycle for the treatment of pancreatic cancer. For the treatment of non-small cell lung cancer, the dose is 1000-1199 mg/m² over 30 minutes on Day 1 only.

**SIDE EFFECTS**

The most common side effects associated with Gemcitabine for Injection therapy are nausea, vomiting, diarrhea, and stomatitis. These side effects are usually mild to moderate in intensity.

**RECOMMENDATIONS**

Gemcitabine for Injection is administered as a single intravenous dose in a diluent solution. It is important to ensure that the solution is mixed properly before administration. The solution should be administered slowly to avoid the risk of extravasation. Patients should be monitored closely for any signs of toxicity.

**REFERENCES**

For a complete list of references, please refer to the prescribing information provided by the manufacturer. Gemcitabine for Injection is available in the USA from [manufacturer name].
The safety and effectiveness of Gemcitabine for Injection in pediatric patients has not been established. Gemcitabine for Injection was administered in pregnant rats at doses of 0.1 mg/kg/day (about 1/600 the recommended human dose on a mg/m2 basis) during gestation. No fetal abnormalities were observed. However, the structural integrity of the fetal gall bladder was altered in a mouse lymphoma (L5128Y) assay. No confirmed objective tumor responses were observed with either treatment. Overall Survival (N=14) 24% (95%, C.I. months). Female patients were administered more frequently with combination therapy than with monotherapy (granulocyte growth factors: 23.6% and 14.5%, respectively). The half-life of the terminal phase of the plasma decay of Gemcitabine for Injection is 40.7 hours after intravenous administration in male patients younger than 65. The plasma decay of Gemcitabine for Injection is 30.9% in patients younger than 65 and 30.7% in patients 65 years of age or older. These differences in the half-life and plasma decay among patients were observed in patients ≥ 65 years of age. Interpatient variability may be observed.

Table 14: Gemcitabine for Injection Versus 5-FU in Pancreatic Cancer
Characteristics
Unsteadiness
Vomiting
Neutropenia
Alopecia
30
75
15
40
79
8.7  Hepatic
The concentration of gemcitabine for any given dose. Differences in either clearance or volume of distribution based on patient characteristics were not observed. Differences in either clearance or volume of distribution based on patient characteristics were not observed. Differences in either clearance or volume of distribution based on patient characteristics were not observed. Differences in either clearance or volume of distribution based on patient characteristics were not observed.

Table 16: Summary of Observed Complications in NCT00094065
Expanding (≥30 mm) vs. Stable (≤30 mm) at Time of Enrollment

In addition to blood product transfusions as listed in Table 8, myelosuppression was also managed with hematopoietic agents. These adverse reactions have occurred after Gemcitabine for Injection single-agent use and Gemcitabine for Injection in combination with gemcitabine for Injection plus cisplatin. These adverse reactions have occurred after Gemcitabine for Injection single-agent use and Gemcitabine for Injection in combination with gemcitabine for Injection plus cisplatin. These adverse reactions have occurred after Gemcitabine for Injection single-agent use and Gemcitabine for Injection in combination with gemcitabine for Injection plus cisplatin.

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