Spike & Go™!

INFUGEM™ is the first and only FDA-approved **ready-to-infuse** final dosage form of gemcitabine[1-3]

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

INDICATIONS AND USAGE

INFUGEM is a nucleoside metabolic inhibitor indicated for:

Ovarian Cancer: in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

Breast Cancer: 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.

Non-Small Cell Lung Cancer: in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer.

Pancreatic Cancer: as first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. INFUGEM is indicated for patients previously treated with fluorouracil.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INFUGEM is contraindicated in patients with a known hypersensitivity to gemcitabine.

Please see additional Important Safety Information throughout this booklet and accompanying full Prescribing Information.

Complex Chemotherapy Compounding

Traditionally, compounding has been necessary because chemotherapy products were only available in forms that were not ready for administration, such as freeze-dried powders or concentrated solutions.[4] INFUGEM™ eliminates some of the many compounding steps required with other gemcitabine products.[1]

Inherent concerns with all compounding[5-7]:

EXPOSURE

Inadvertent drug exposure to pharmacists and healthcare workers

RISKS

Product variability, contamination, and medication errors

COMPLEXITY

A complex compounding process requires many steps and materials

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS

Schedule-Dependent Toxicity: In clinical trials evaluating the maximum tolerated dose of gemcitabine, prolongation of the infusion time beyond 60 minutes or more frequent than weekly dosing resulted in an increased incidence of clinically significant hypotension, severe flu-like symptoms, myelosuppression, and asthenia.

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INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Latest Guidelines Call for Using **Ready-to-Administer** Products

Raising Safety Standards

Organizations increasingly call for using the most ready-to-administer drug products available.[5-7]

» Commercially prepared, premixed parenteral products should be used to the maximum extent, whenever possible.

– INSTITUTE FOR SAFE MEDICATION PRACTICES (ISMP)

» Whenever possible, medications should be available for inpatient use in ready-to-administer packaging without further manipulation by the person administering the medication.

– AMERICAN SOCIETY OF HOSPITAL PHARMACISTS (ASHP) GUIDELINES

» Medications in patient care areas should be available in the most ready-to-administer forms commercially available.

– THE JOINT COMMISSION

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS – continued

Myelosuppression: Myelosuppression manifested by neutropenia, thrombocytopenia, and anemia occurs with INFUGEM as a single agent, and the risks are increased when INFUGEM is combined with other cytotoxic drugs. Monitor patients receiving INFUGEM prior to each dose with a complete blood count (CBC), including differential and platelet count, and modify the dosage as recommended.

Please see additional Important Safety Information throughout this booklet and accompanying full Prescribing Information.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Spike & Go™!

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

- INFUGEM™ is the first and only FDA-approved gemcitabine in a ready-to-infuse, final dosage formulation[1-3]
- INFUGEM provides pharmacists with the only FDA-approved final dosage form of gemcitabine that meets The Joint Commission standard for using the most ready-to-administer form available.[1,7]

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS – continued
Pulmonary Toxicity and Respiratory Failure: Permanently discontinue INFUGEM in patients who develop unexplained dyspnea, with or without bronchospasm, or have any evidence of pulmonary toxicity.
Hemolytic Uremic Syndrome: Hemolytic uremic syndrome (HUS), including fatalities from renal failure or the requirement for dialysis, can occur in patients treated with INFUGEM. Assess renal function prior to initiation of INFUGEM and periodically during treatment. Consider the diagnosis of HUS in patients who develop anemia with evidence of microangiopathic hemolysis, elevation of bilirubin or LDH, or reticulocytosis; severe thrombocytopenia; or evidence of renal failure (elevation of serum creatinine or BUN). Permanently discontinue INFUGEM in patients with HUS or severe renal impairment. Renal failure may not be reversible even with discontinuation of therapy.

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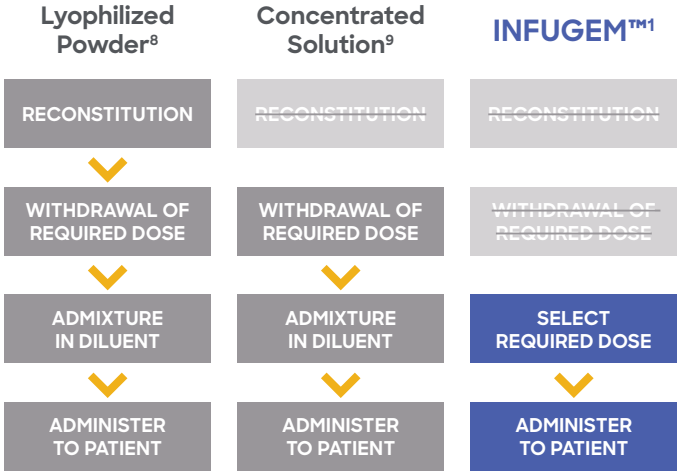
Eliminate Steps in Chemotherapy Preparation

Compounding cytotoxic drugs requires a multistep process that presents multiple opportunities for error, contamination, and accidental exposure.[3]



Using INFUGEM™ **eliminates steps** in gemcitabine preparation.[1]

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS – continued

Hepatic Toxicity: Drug-induced liver injury, including liver failure and death, has been reported in patients receiving gemcitabine alone or in combination with other potentially hepatotoxic drugs. Administration of INFUGEM in patients with concurrent liver metastases or a preexisting medical history of hepatitis, alcoholism, or liver cirrhosis can lead to exacerbation of the underlying hepatic insufficiency. Assess hepatic function prior to initiation of INFUGEM and periodically during treatment. Permanently discontinue INFUGEM in patients that develop severe liver injury.

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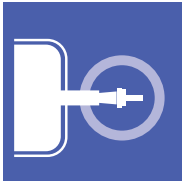
INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Innovative Design Developed With Healthcare Workers' Safety in Mind

COMPOSITION

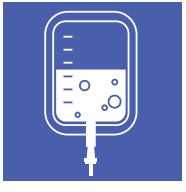
INFUGEM™ is a clear, colorless, sterile solution of 10 mg/mL gemcitabine in 0.9% sodium chloride that is alcohol free.[1]

PROTECTION



The INFUGEM infusion bags are pre-fitted with a trocar-connected Minitulipe® infusion port with a breakable tamper-evident extension to protect the infusion site and reduce the risk of contamination.[1]

DESIGN



INFUGEM is supplied in single-dose, premixed, intravenous infusion bags made of polyolefin plastic with an aluminum overwrap to protect against inadvertent exposure.[1]

SECURITY

INFUGEM bags are packaged in aluminum pouches and hard carton boxes to protect them from accidental puncture and mechanical stress.[1]

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS – continued

Embryo-Fetal Toxicity: INFUGEM can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with INFUGEM and for 6 months after the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during and for 3 months following the final dose of INFUGEM.

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INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Designed to Fit Well Within Your Clinical Practice

- INFUGEM™ is stable for 24 months at room temperature storage conditions (68°F to 77°F)[1,10]
- INFUGEM is available in 10 dosage units ranging from 120 mL to 220 mL, equivalent to 1200 mg to 2200 mg of premixed gemcitabine per infusion bag[1]
- Infusion bag packaging is color-coded and bar-coded to correspond with each of the 10 different dosage strengths and facilitate dose identification[1,10]

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS – continued

Exacerbation of Radiation Therapy Toxicity: INFUGEM is not recommended for use in combination with radiation therapy. Concurrent (given together or ≤7 days apart) – Life-threatening mucositis, especially esophagitis and pneumonitis occurred in a trial in which gemcitabine was administered at a dose of 1000 mg/m^2 to patients with non-small cell lung cancer for up to 6 consecutive weeks concurrently with thoracic radiation.

Non-concurrent (given >7 days apart) – Excessive toxicity has not been observed when gemcitabine is administered more than 7 days before or after radiation. Radiation recall has been reported in patients who receive gemcitabine after prior radiation.

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INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

INFUGEM™ Dosing

INFUGEM comes premixed and ready to infuse, and is available in 10 SKUs with color-coded labeling[1]

- Dose and frequency of administration is dependent upon indication for use
- Intravenous infusion of 1000 mg/m^2 or 1250 mg/m^2 is administered over 30 minutes. If 2 premixed infusion bags are required to achieve the prescribed dose, infuse the total volume of both bags over 30 minutes
- For doses less than 1150 mg, another formulation of gemcitabine is recommended

1,200 mg per 120 mL (10 mg/mL)	1,700 mg per 170 mL (10 mg/mL)
1,300 mg per 130 mL (10 mg/mL)	1,800 mg per 180 mL (10 mg/mL)
1,400 mg per 140 mL (10 mg/mL)	1,900 mg per 190 mL (10 mg/mL)
1,500 mg per 150 mL (10 mg/mL)	2,000 mg per 200 mL (10 mg/mL)
1,600 mg per 160 mL (10 mg/mL)	2,200 mg per 220 mL (10 mg/mL)

Available doses of INFUGEM

IMPORTANT SAFETY INFORMATION – continued

WARNINGS AND PRECAUTIONS – continued

Capillary Leak Syndrome: Capillary leak syndrome (CLS) with severe consequences has been reported in patients receiving gemcitabine as a single agent or in combination with other chemotherapeutic agents. Permanently discontinue INFUGEM if CLS develops during therapy.

Posterior Reversible Encephalopathy Syndrome: Posterior reversible encephalopathy syndrome (PRES) has been reported in patients receiving gemcitabine as a single agent or in combination with other chemotherapeutic agents. PRES can present with headache, seizure, lethargy, hypertension, confusion, blindness, and other visual and neurologic disturbances. Confirm the diagnosis of PRES with magnetic resonance imaging (MRI) and permanently discontinue INFUGEM if PRES develops during therapy.

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INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

FDA-Recommended Dose Selection

- Practitioners can follow FDA-approved tables to select appropriate dose[1]
- Based on the calculated dose, 1 or 2 INFUGEM™ bags may be needed per administration[1]
- INFUGEM premixed bag(s) allow for a variance of up to 5% of the BSA-calculated dose, following FDA guidance[1]

Examples of INFUGEM Bag Selection by Dose and BSA[1*]

PRESCRIBED DOSE	BSA RANGE	CALCULATED DOSE RANGE	INFUGEM BAG(s) NEEDED
1000 mg/m^2	1.46 – 1.55	1455 mg to 1554 mg	1,500 mg per 150 mL (10 mg/mL)
1250 mg/m^2	2.29 – 2.36	2857 mg to 2956 mg	1,200 mg per 120 mL (10 mg/mL) 1,700 mg per 170 mL (10 mg/mL)

*See Instructions for Use for the full FDA-approved dose selection tables.
FDA=US Food and Drug Administration; BSA=body surface area.

IMPORTANT SAFETY INFORMATION – continued

ADVERSE REACTIONS
The most common adverse reactions for the single agent (≥20%) are nausea/vomiting, anemia, hepatic transaminitis, neutropenia, increased alkaline phosphatase, proteinuria, fever, hematuria, rash, thrombocytopenia, dyspnea, and peripheral edema.

USE IN SPECIFIC POPULATIONS
Due to the potential for serious adverse reactions in nursing infants from INFUGEM, woman should not breastfeed during treatment with INFUGEM and for at least one week after the last dose.

The safety and effectiveness of INFUGEM have not been established in pediatric patients.

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ADDITIONAL IMPORTANT SAFETY INFORMATION continued on next page.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

IMPORTANT SAFETY INFORMATION - continued
WARNINGS AND PRECAUTIONS - continued

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INFUGEM™
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Ordering INFUGEM™

To place an order, contact your wholesaler

For more information, visit **infugem.com** or contact your Sun Oncology Sales Representative.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

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