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Sun Pharma launches ready-to-infuse INFUGEM in the US

08 April 2019 | News

INFUGEM is the first and only chemotherapy product in a premixed, ready-to-infuse formulation

Sun Pharmaceutical Industries Ltd. has announced that INFUGEM™ (gemcitabine in sodium chloride injection), for intravenous use, is now commercially available in the U.S. INFUGEM, the first chemotherapy product that comes in a premixed, ready-to-infuse formulation, was approved by the U.S. Food and Drug Administration (FDA) in July 2018 in combination with other drugs for the treatment of breast, ovarian, non-small cell lung cancers, and as a single agent for the treatment of pancreatic cancer.

INFUGEM is an alcohol-free, clear, colorless, sterile solution of 10mg/mL gemcitabine in 0.9% sodium chloride that is supplied to pharmacists in ready-to-infuse bags as a Spike & Go™ package. It involves dose banding practice, whereby standardized doses of intravenous cytotoxic drugs are used for ranges (or “bands”) of doses calculated for individual patients. INFUGEM is the only available gemcitabine formulation that does not require reconstitution and syringe withdrawal prior to intravenous administration. Eliminating these steps reduces complexity and minimizes the inherent risks of hazardous drug exposure, contamination, and medication errors.

INFUGEM is the first product using Sun’s proprietary technology which allows cytotoxic oncology products to be premixed in a sterile environment and supplied to the prescribers in ready-to-infuse final dosage bags. The product is stable at room temperature storage conditions for two years, even without the use of alcohol and other preservatives in the bag. By contrast, other gemcitabine products require reconstitution and/or dilution for patient use, and remain stable at room temperature for only 24 hours.