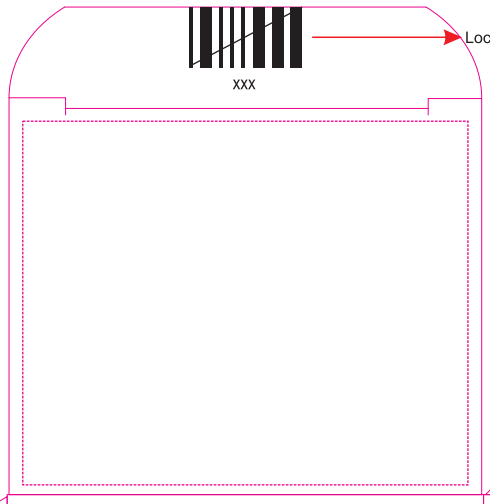
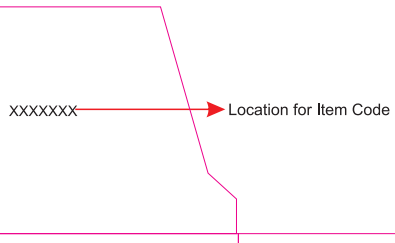


Batch No. : xxxxxxxxxx
Mfg. Date : xxxxxxxxxx
Exp. Date : xxxxxxxxxx
above details along with variable data or 2D data matrix shall be printed during packing (unvarnished Area)



pharmaniaga®

GEMITOX

38 mg/mL Concentrate for Solution for Infusion

Caution: Cytotoxic Agent

1 g/ 26.3 mL
FOR IV INFUSION ONLY

1g/26.3ml

Each mL contains **gemcitabine hydrochloride** equivalent to 38 mg gemcitabine

Unopened vial: Store in a refrigerator (2°C-8°C).

For storage conditions after dilution of the medicinal product:
In-Use: Further dilution
After dilution, chemical and physical in-use stability has been demonstrated for:

Diluent	Target Concentration	Storage Conditions	Time period
0.9% sodium chloride solution for infusion	0.1 mg/ml and 26 mg/ml	2-8°C in the absence of light in non-PVC (polyolefin) infusion bags	24 hours
0.9% sodium chloride solution for infusion	0.1 mg/ml and 26 mg/ml	2-8°C in the absence of light in PVC infusion bags	24 hours
0.9% sodium chloride solution for infusion	0.1 mg/ml and 26 mg/ml	25°C under normal lighting conditions in PVC infusion bags	6 hours
5% glucose solution for infusion	0.1 mg/ml and 26 mg/ml	25°C under normal lighting conditions in PVC infusion bags	6 hours

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

CONTROLLED MEDICINE (UBAT TERKAWAL)

pharmaniaga®

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1 g/ 26.3 mL
FOR IV INFUSION ONLY

1g/26.3ml

Code: TS/DRUGS/1/2013
MAL25036161AZ

Product Registration Holder:
InspiraPharma Sdn. Bhd.
Lot 24 & 25, Jalan 8, Kawasan Perusahaan Bakar Arang,
08000 Sungai Petani,
Kedah Darul Aman, Malaysia

Manufacturer:
Shilpa Medicare Limited
Unit IV, Plot S-20 To S-26, Pharma SEZ, TSIIC, Green Industrial Park,
Polepally (V) Jadcherla (Md),
Mahabubnagar (Dt.),
Telangana - 509301, India

pharmaniaga®

GEMITOX

38 mg/mL Concentrate for Solution for Infusion

Caution: Cytotoxic Agent

1 g/ 26.3 mL
FOR IV INFUSION ONLY

1g/26.3ml

Size: 63x53x87 mm