

GEMCITABINE – DRUG SAFETY INFORMATION

Form: Gemcitabine Hydrochloride 40mg/mL solution for Intravenous injection

General:

- If there is evidence of damage to the packaging in transit please contact us prior to administration.
- Keep out of the reach and sight of children.
- Protect product from light and store at 2-8°C (in the refrigerator) until ready to use.
- The expiry date for the product under the recommended storage conditions will be stated on the label.
- **Single use only:** discard any unused contents.
- For safety, any unused product or chemotherapy contaminated waste materials should be disposed of in accordance with local requirements for handling of cytotoxic waste.

Handling and administration:

Do not eat, drink or smoke in drug handling or administration areas.

Gemcitabine is a cytotoxic drug and should only be handled by adequately trained personnel wearing appropriate personal protective equipment (PPE). Staff members who are pregnant or trying to conceive should not be involved in the administration of the medication or be present in the immediate work environment when the drug is being administered. Likewise they should not come into contact with the patient's urine, faeces, saliva or vomitus after treatment. Nursing staff involved in the care of hospitalised patients that have received chemotherapy should wear appropriate PPE for handling.

Gemcitabine is administered with 0.9% sodium chloride as an intravenous infusion. Preparation of the infusion should be performed in a designated, 'low traffic' area.

Prevention of contamination:

- Routes of exposure to chemotherapy agents include ingestion, inhalation, and absorption through the skin and mucous membranes.
- PPE (eye protection, face mask, gloves and protective gowns) should be worn by the vet and handler during drug administration and disposal of contaminated waste.
- The work surface under the patient should be covered with a disposable plastic-backed work mat.
- Skin accidentally exposed to gemcitabine should be rinsed copiously with warm water and if the eyes are involved standard irrigation techniques should be used. Medical advice should be sought immediately.

Spill management:

If gemcitabine is spilled on equipment or environmental surfaces, non-essential personnel should be instructed not to enter the area. Wearing appropriate PPE, the spillage should be mopped up with absorbent pads. A detergent and water solution should be used to wash and clean the area and dry tissues should be used to absorb the cleaning solution. Following cleansing, the area is rinsed twice with clean water and dried. Absorbent materials and PPE should be disposed of as contaminated cytotoxic waste.

Disposal:

Absorbent materials and disposables that have potentially come into contact with gemcitabine should be disposed of in appropriate cytotoxic waste containers prior to incineration.

Warnings and contraindications:

(At risk groups include pregnant or lactating women, women or men trying to conceive, young children, the elderly or patients receiving chemotherapy themselves).

- Similar to all chemotherapy agents, treatment with gemcitabine is associated with toxicity in normal tissues including bone marrow suppression (myelosuppression), gastrointestinal toxicity, reproductive failure and alopecia in certain breeds.
- Local tissue toxicities and myelosuppression can be severe when gemcitabine is used as a radiation sensitising agent.
- Concurrent use of other myelosuppressive agents should be avoided unless clinically indicated.
- Peripheral blood counts, with particular attention to neutrophil and platelet numbers should be monitored closely during treatment.
- Drug residues may be found in the urine and faeces of treated patients for up to **7 days** after treatment and owners must be warned about this hazard. Individuals in at risk groups should be particularly careful to avoid contact with patient excreta or saliva.
- For canine patients, faeces should be double bagged for clean-up and water should be poured over areas where a pet urinates outdoors to dilute any residues. For cats, the litter box should be cleaned every day taking adequate care when handling and bagging any contaminated litter material.

Further information:

Further information is available on request by contacting us at info@chemopet.co.uk or by telephone: 01928 250052.