GEMITRATE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for GEMITRATE [Gemcitabine hydrochloride 200mg, 1gm and 1.4gm lyophilized injection] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Gemcitabine is a nucleoside metabolic inhibitor that exhibits antitumor activity.

INDICATION: In management of non-small cell lung cancer, bladder cancer, ovarian cancer and breast cancer.

DOSAGE AND ADMINISTRATION: For IV infusion, upon reconstitution a colourless or slightly yellow solution is produced. Gemitrate 200: reconstitute with 5 ml of sodium chloride injection (0.9% w/v) and shake gently to make a clear solution containing 38 mg/ml to 40 mg/ml of gemcitabine. Gemitrate 1000: reconstitute with 25 ml of sodium chloride injection (0.9% w/v) and shake gently to make a clear solution containing 38 mg/ml to 40 mg/ml of gemcitabine. Reconstitution at concentrations greater than 40 mg/ml may result in incomplete dissolution and should be avoided. The recommended dose for bladder cancer, pancreatic cancer, non-small cell lung cancer and ovarian cancer is 1000 mg/m^2, given as a 30 minute infusion and for breast cancer recommended dose of gemcitabine(1250 mg/m^2) is used together with paclitaxel (175 mg/m^2).

CONTRAINDICATION: In patients with known hypersensitivity to gemcitabine or to any of the excipients and breast-feeding.

WARNINGS & PRECAUTIONS: Prolongation of the infusion time beyond 60 minutes or more frequent resulted in an increased incidence of hypotension, severe flu-like symptoms, myelosuppression manifested by neutropenia, thrombocytopenia, and anemia occurs with gemcitabine as a single agent and the risks are increased when gemcitabine is combined with other cytotoxic drugs. Life-threatening mucositis, especially esophagitis and pneumonitis, pulmonary toxicity, including interstitial pneumonitis, pulmonary fibrosis, pulmonary edema, and adult respiratory distress syndrome (ARDS), drug-induced liver injury, hemolytic uremic syndrome ,capillary leak syndrome (CLS) and posterior reversible encephalopathy syndrome (PRES) has been reported.

ADVERSE REACTIONS: Leucopenia, bone marrow suppression, febrile neutropenia, anorexia, headache, insomnia, somnolence, dyspnea, cough, rhinitis, vomiting, nausea, diarrhea, stomatitis and ulceration of the mouth, elevation of liver transaminases and alanine aminotransferase (ALT)) and alkaline phosphatase, increased bilirubin, allergic skin rash frequently associated with pruritus, alopecia, itching and sweating, back pain, myalgia, haematuria, mild proteinurea, fever, headache, chills, asthenia, anorexia, cough, rhinitis, malaise, perspiration and sleeping difficulties, oedema/peripheral oedema-including facial oedema and radiation toxicity.

MARKETED BY:

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IN/GEMITRATE 200mg,1gm and 1.4gm /Jun-15/01/ABPI

(Additional information is available on request)