

TORRENCE

For the use of Oncologist or a Hospital or a Laboratory only

Abbreviated Prescribing information for TORRENCE (Epirubicin Hydrochloride 10 mg, 50 mg for Injection) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: Epirubicin is an anthracycline cytotoxic agent.

INDICATIONS: Carcinoma of the breast, Gastric cancer, Lung cancer.

DOSAGE AND ADMINISTRATION: When epirubicin is used as a single agent, the recommended dosage in adults is 60-90 mg/m² body area. Epirubicin should be injected intravenously over 3-5 minutes. The dose should be repeated at 21-day intervals, depending upon the patient's haematomedullary status. High Dose: Epirubicin as a single agent for the high dose treatment of lung cancer {Small cell lung cancer (previously untreated)}: 120 mg/m² day 1, every 3 weeks. For high dose treatment, epirubicin may be given as an intravenous bolus over 3-5 minutes or as an infusion of up to 30 minutes duration. Breast cancer: In the adjuvant treatment of early breast cancer patients with positive lymph nodes, intravenous doses of epirubicin ranging from 100 mg/m² (as a single dose on day 1) to 120 mg/m² (in two divided doses on days 1 and 8) every 3-4 weeks, in combination with intravenous cyclophosphamide and 5-fluorouracil and oral tamoxifen.

CONTRAINDICATIONS: baseline neutrophil count <1500 cells/mm³; Severe hepatic impairment, recent myocardial infarction; severe myocardial insufficiency; severe arrhythmias, hypersensitivity to doxorubicin, Severe liver impairment, Severe arrhythmias, Unstable angina pectoris Myocardiopathy.

WARNINGS AND PRECAUTIONS: Severe local tissue necrosis, Myocardial toxicity, Secondary acute myelogenous leukemia, hepatotoxicity, neutropenia, hypersensitivity reactions and fluid retention.

DRUG INTERACTIONS: Paclitaxel: increases cytotoxicity, Progesterone: Enhanced toxicity, Cyclosporine: Increased neutropenia, Cytarabine: increased toxicity.

ADVERSE REACTIONS: Sinus tachycardia, Tachyarrhythmias, premature ventricular contractions and ventricular tachycardia, bradycardia, alopecia; Hyperpigmentation of nailbeds and dermal creases; onycholysis; Rash, itching, or photosensitivity, Acute nausea and vomiting; Mucositis, Myelosuppression, Fever, chills, and urticaria, Peripheral neurotoxicity.