ADRIFAST

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

Abbreviated Prescribing information for ADRIFAST (Doxorubicin Hydrochloride 10, 50 mg Injection I.P.) [Please refer the complete prescribing information for details]

PHARMACOLOGICAL PROPERTIES: (Antineoplastic) Cytotoxic effect of doxorubicin is thought to be related to nucleotide base intercalation and cell membrane lipid binding activities.

INDICATIONS: To produce regression in disseminated neoplastic conditions such as Acute lymphoblastic leukemia, Acute myeloblastic leukemia, Wilms' tumor, Neuroblastoma, Soft tissue and bone sarcomas, breast carcinoma, ovarian carcinoma, transitional cell bladder carcinoma, thyroid carcinoma,gastric carcinoma, Hodgkin's disease, Malignant lymphoma, and bronchogenic carcinoma, in which the small cell histologic type is the most responsive compared to other cell types, as a component of adjuvant therapy in women with evidence of axillary lymph node involvement following resection of primary breast cancer.

DOSAGE AND ADMINISTRATION: When used as a single agent: 60 to 75 mg/m2 as a single intravenous injection administered at 21-day intervals. When used in combination with other chemotherapy drugs: most commonly used dosage of doxorubicin is 40 to 60 mg/m2 given as a single intravenous injection every 21 to 28 days

CONTRAINDICATIONS: Baseline neutrophil count <1500 cells/mm3; Severe hepatic impairment, recent myocardial infarction; severe myocardial insufficiency; severe arrhythmias,Previous treatment with complete cumulative doses of doxorubicin,daunorubicin, idarubicin, and/or other anthracyclines and anthracenediones; or hypersensitivity to doxorubicin, any of its excipients, or other anthracyclines or anthracenediones

WARNINGS AND PRECAUTIONS: Severe local tissue necrosis, myocardial toxicity, hepatotoxicity, neutropenia, hypersensitivity reactions and fluid retention, Secondary acute myelogenous leukemia (AML) or myelodysplastic syndrome (MDS), Immunosuppressant Effects/Increased Susceptibility to Infections.

DRUG INTERACTIONS: Paclitaxel: increases cytotoxicity, Progesterone: enhanced toxicity, Cyclosporine: increase neutropenia, Cytarabine: increased toxicity Cyclophosphamide: does not affect exposure to doxorubicin, but may result in an increase in exposure to doxorubicinol.

ADVERSE REACTIONS: Sinus tachycardia, Tachyarrhythmia’s, premature ventricular contractions and ventricular tachycardia, bradycardia, alopecia; Hyperpigmentation of nail beds and dermal creases; onycholysis; Rash, itching, or

photosensitivity, Acute nausea and vomiting; Mucositis, Myelosuppression, Fever, chills, and urticaria, Peripheral neurotoxicity.