TORTAXEL

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

Abbreviated Prescribing information for TORTAXEL (Paclitaxel 30 mg, 100 mg & 260 mg Injection I.P.) [Please refer the complete prescribing information for details**]**

PHARMACOLOGICAL PROPERTIES: (Antineoplastic) Novel antimicrotubule agent that promotes the assembly of microtubules from tubulin dimers.

INDICATIONS: First-line and subsequent therapy for the treatment of advanced carcinoma of the Ovary, Adjuvant treatment of node-positive breast cancer, Paclitaxel in combination with cisplatin, is indicated for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy, Second linetreatment of AIDS-related Kaposi's sarcoma.

DOSAGE ANDADMINISTRATION: Carcinoma of the ovary previously not treated with chemotherapy: Intravenously over 3 hours at a dose of 175 mg/m^2 followed by Cisplatin at a dose of 75 mg/m2. Second regimen: Intravenously over 24 hours at a dose of 135 mg/m^2, Adjuvant treatment of node-positive breast cancer: The recommended regimen is Paclitaxel, at a dose of 175 mg/m^2 intravenously over 3 hours every 3 weeks for 4 courses administered sequentially to doxorubicin-containing combination chemotherapy, For patients with AIDS related Kaposi's sarcoma: At a dose of 135 mg/m^2 given intravenously over 3 hours every 3 weeks or at a dose of 100 mg/m^2 givenintravenously over 3 hours every 2 weeks.

CONTRAINDICATIONS: During lactation, Paclitaxel should not be used in patients with baseline neutrophils< 1.5 x 109/L (< 1 x 109/L for AIDS-related Kaposi's sarcoma (KS) patients)or platelets < 100 x 109/L (< 75 x 109/L for KS patients), In KS, Paclitaxel is also contraindicated in patients with concurrent, serious, uncontrolled infections.

WARNINGS AND PRECAUTIONS: Significant hypersensitivity reactions, Severe cardiac conduction abnormalities, Peripheral neuropathy, Decreased Renal Function, Bone Marrow Suppression, Hepatic impairment, Pseudomembranous colitis.

DRUG INTERACTIONS: Doxorubicin: increased concentration of doxorubicin given after 24 hrs.

ADVERSE REACTIONS: Neutrophils, Granulocytes decreased, Leucocytes decreased Hemoglobin decreased, Platelets decreased, Dehydration, Neuropathy, Taste disturbances, Diarrhoea, Vomiting, Nausea, Constipation, Rash, Alopecia, Creatinine Clearance decreased, Fatigue, Bradycardia, Cardiomyopathy, asymptomatic ventricular tachycardia, Neurotoxicity.