TORTAXEL

For the use of Oncologist or a Hospital or a Laboratory

Abbreviated Prescribing information for TORTAXEL [Paclitaxel Injectable I.P.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Paclitaxel is a novel antimicrotubular agent that promotes the assembly of microtubules from tubulin dimers and stabilises microtubules by preventing depolymerization.

INDICATIONS: Paclitaxel is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. For the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. For the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. 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. For the second-line treatment of AIDS-related Kaposi's sarcoma.

DOSAGE AND ADMINISTRATION: For patients with carcinoma of the ovary: 1) For previously untreated patients with carcinoma of the ovary. • Intravenously over 3 hours at a dose of 175 mg/m^2 followed by cisplatin at a dose of 75 mg/m^2; or, • Intravenously over 24 hours at a dose of 135 mg/m^2 followed by cisplatin at a dose of 75 mg/m^2. 2) In patients previously treated with chemotherapy for carcinoma of the ovary. The recommended regimen is paclitaxel 135 mg/m^2 or 175 mg/m^2 administered intravenously over 3 hours every 3 weeks; For patients with carcinoma of the breast: 1) For the 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 non-small cell lung carcinoma: the recommended regimen, given every 3 weeks, is Paclitaxel administered intravenously over 24 hours at a dose of 135 mg/m^2 followed by cisplatin, 75 mg/m^2, 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 given intravenously over 3 hours every 2 weeks is recommended (dose intensity 45–50 mg/m^2/week). In the 2 clinical trials evaluating these schedules, the former schedule (135 mg/m^2 every 3 weeks) was more toxic than the latter. The drug should be administered with caution in the following patients, Paclitaxel Injection should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents.

CONTRAINDICATION: • Hypersensitivity to the active substance or to any of the excipients, especially Polyoxyethylated 35 castor oil (Macrogolglycerol ricinoleate 35) • Lactation. • Patients with baseline neutrophils < 1,500/mm^3 (<1,000/mm^3 for KS patients). • In KS, patients with concurrent, serious, uncontrolled infections.

WARNINGS & PRECAUTIONS: Significant hypersensitivity reactions characterised by dyspnoea and hypotension requiring treatment, angioedema and generalised urticaria have occurred in < 1% of patients receiving paclitaxel after adequate premedication. Bone marrow suppression (primarily neutropenia) is the dose-limiting toxicity. Patients with severe neutropenia (< 500 cells/mm3 for 7 days or more) during a course of paclitaxel or neutropenic sepsis should have their dose of paclitaxel reduced for subsequent courses of paclitaxel. Patients with hepatic impairment may be at increased risk of toxicity, particularly grade III-IV myelosuppression. Severe cardiac conduction abnormalities have been reported rarely with single agent paclitaxel. Although the occurrence of peripheral neuropathy is frequent, the development of severe symptoms is rare. Others: Special care should be taken to avoid intra-arterial application of paclitaxel. Paclitaxel in combination with radiation of the lung, irrespective of their chronological order, may contribute to the development of interstitial pneumonitis. Paclitaxel concentrate for solution for

infusion contains Polyoxyl Castor oil, which may cause severe allergic reactions. Pseudomembranous colitis has been rarely reported including cases in patients who have not been concomitantly treated with antibiotics. Paclitaxel has shown to be teratogenic, embryotoxic and mutagenic in many experimental systems.

DRUG INTERACTIONS: The recommended regimen of paclitaxel administration for the first-line chemotherapy of ovarian carcinoma is for paclitaxel to be given before cisplatin. Since the elimination of doxorubicin and its active metabolites can be reduced when paclitaxel and doxorubicin are given closer in time. The metabolism of paclitaxel is catalysed, in part, by cytochrome P450 isoenzymes CYP2C8 and 3A4. Paclitaxel clearance is not affected by cimetidine premedication. The systemic clearance of paclitaxel was significantly lower in the presence of nelfinavir and ritonavir, but not with indinavir

ADVERSE REACTIONS: Infection, flu syndrome, septic shock, pneumonia, myelosuppression, neutropenic fever, severe anaemia, febrile neutropenia, acute myeloid leukaemia, minor hypersensitivity reactions, significant hypersensitivity reactions requiring therapy, anaphylactic reactions, anaphylatic shock, weight gain, anorexia, tumour lysis syndrome, confusional stage, neurotoxicity, depression, motor neuropathy, autonomic neuropathy, dry eyes, optic nerve and/or visual disturbances, macular oedema, ototoxicity, bradycardia, cardiomyopathy, cardiac failure, atrial fibrillation, hypotension, vasodilatation, hypertension, shock, phlebitis, epistaxis, dyspnoea, cough, nausea, dry mouth, bowel obstruction, mesenteric thrombosis, hepatic necrosis, alopecia, transient and mild nail and skin changes, changes in nail pigmentation, pruritus, stevens-johnson syndrome, scleroderma, arthralgia, bone pain, systemic lupus erythematosus, asthenia, injection site reactions, dysuria, severe elevation in AST, severe elevation in bilirubin, increase in blood creatinine.

MARKETED BY:

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IN/TORTAXEL/MAR 2026/02/ABPI

(Additional information is available on request)