

DTAXANE

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

Abbreviated Prescribing information for Dtaxane (Docetaxel Injection 20/80/120mg Concentrate) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Docetaxel belongs to the taxoid family and acts by disrupting the microtubular network in cells that is essential for mitotic and interphase cellular functions. **INDICATION:** Breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma and head and neck cancer. **DOSAGE AND ADMINISTRATION:** Reconstitute concentrate after bringing it to room temperature using 1.5 ml solvent pack for 20 mg, 6 ml solvent pack for 80 mg and 9 ml solvent pack for 120 mg. Rotate the vial gently and allow the premix to stand for 5 minutes. The solution should be clear and homogenous. Use this docetaxel premix for further dilution. Breast cancer: 75 mg/m² administered 1 hour after doxorubicin 50 mg/m² and cyclophosphamide 500 mg/m² every 3 weeks for 6 cycles (TAC regimen). Non-small cell lung cancer: 75 mg/m² immediately followed by cisplatin 75 mg/m² over 30-60 minutes. Prostate cancer: 75 mg/m². Gastric adenocarcinoma: 75 mg/m² as a 1-hour infusion, followed by cisplatin 75 mg/m², as a 1 to 3-hour infusion (both on day 1 only), followed by 5 fluorouracil 750 mg/m² per day given as a 24 hour continuous infusion for 5 days, starting at the end of the cisplatin infusion. Induction therapy of head and neck cancer: Recommended dose is 75 mg/m² as a 1 hour infusion followed by cisplatin 75 mg/m² over 1 hour, on day one, followed by 5 fluorouracil as a continuous infusion at 750 mg/m² per day for five days for inoperable locally advanced squamous cell carcinoma of the head and neck (SCCHN) and 75 mg/m² as a 1 hour intravenous infusion on day 1, followed by cisplatin 100 mg/m² administered as a 30-minute to 3-hour infusion, followed by 5-fluorouracil 1000 mg/m²/day as a continuous infusion from day 1 to day 4 for locally advanced (technically unresectable, low probability of surgical cure, and aiming at organ preservation) squamous cell carcinoma of the head and neck (SCCHN). **CONTRINDICATIONS:** In patients with severe hypersensitivity reactions to docetaxel or to other drugs formulated with polysorbate 80, neutrophil counts of < 1,500 cells/mm³ and severe liver impairment. **WARNINGS & PRECAUTIONS:** Toxic deaths in patients with breast cancer and non-small cell lung cancer, hepatic impairment, neutropenia, febrile neutropenia, fatal gastrointestinal bleeding associated with severe drug-induced thrombocytopenia, severe hypersensitivity reactions characterized by generalized rash/erythema, hypotension and/or bronchospasm, or very rarely fatal anaphylaxis, *severe* fluid retention, acute myeloid leukemia, cutaneous reactions, *neurologic reactions* (paresthesia, dysesthesia, pain), cystoid macular edema (cme), alcohol intoxication, and asthenia. **DRUG INTERACTION:** Interacts with ketoconazole, protease inhibitors particularly ritonavir, and drugs that inhibit CYP3A4. **ADVERSE REACTIONS:** infections, anemia, febrile neutropenia, hypersensitivity, thrombocytopenia, neuropathy, dysgeusia, dyspnea, constipation, anorexia, nail disorders, fluid retention, asthenia, pain, nausea, diarrhea, vomiting, mucositis, alopecia, skin reactions, myalgia, chest pain, Atrial fibrillation, deep vein thrombosis, ECG abnormalities, thrombophlebitis, pulmonary embolism, syncope, tachycardia, myocardial infarction, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, Severe hand and foot syndrome, esophagitis, ischemic colitis, Disseminated intravascular coagulation (DIC), hepatitis, seizures, Conjunctivitis, ototoxicity, acute respiratory distress syndrome/pneumonitis, respiratory failure, renal failure and hyponatremia.

MARKETED BY:



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(Additional information is available on request)