

NAB TORTAXEL

For the use of an Oncologists or a Hospital or laboratory only

Abbreviated Prescribing information for **NAB TORTAXEL** [Paclitaxel (Protein-Bound Particles) for Injectable Suspension (100mg)] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Paclitaxel, taxane – plant alkaloid, is an anti-microtubule agent that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing de-polymerisation. **INDICATION:** For the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. **DOSAGE AND ADMINISTRATION:** Breast cancer: 260 mg/m² administered intravenously over 30 minutes every 3 weeks. If patient experiences severe neutropenia (neutrophil count < 500 cells/mm³ for a week or longer) or severe sensory neuropathy dosage reduction is required. Dose adjustment is recommended in metastatic breast cancer with moderate to severe hepatic impairment. Aseptically, reconstitute each vial by injecting 20 mL of 0.9% sodium chloride injection IP. Slowly inject the 20 mL of 0.9% sodium chloride injection IP over a minimum of 1 minute, using the sterile syringe to direct the solution flow onto the inside wall of the vial. Do not inject the 0.9% sodium chloride injection IP directly onto the lyophilized cake to avoid foaming. Once the injection is complete, allow the vial to sit for a minimum of 5 minutes to ensure proper wetting of the lyophilized cake/powder. Gently swirl and/or invert the vial slowly for at least 2 minutes until complete dissolution of any cake/powder occurs. If foaming or clumping occurs, stand solution for at least 15 minutes until foam subsides. Each mL of the reconstituted formulation will contain 5 mg/mL paclitaxel.

CONTRAINDICATION: In patients with hypersensitivity to the active substance or to any of the excipients, baseline neutrophil counts <1500 cells/mm³ and during the lactation period.

WARNINGS & PRECAUTIONS: Properly read and follow entire preparation instruction prior to reconstitution. Bone marrow suppression (neutropenia), sepsis, pneumonitis, hepatic impairment, cardiotoxicity (congestive heart failure and left ventricular dysfunction), CNS metastases and GI abnormality. Erlotinib should not be coadministered with paclitaxel (protein-bound particles) for injectable suspension plus gemcitabine.

DRUG INTERACTIONS: Interacts with CYP2C8 and CYP3A4 inducers/inhibitors.

ADVERSE REACTIONS: Hypersensitivity reaction, increased lacrimation, blurred vision, dry eye, keratoconjunctivitis sicca, madarosis, urinary tract infection, folliculitis, upper respiratory tract infection, candidiasis, sinusitis, pain, tumor necrosis, neutropenia, anaemia, leukopenia, thrombocytopenia, lymphopenia, bone marrow suppression, febrile neutropenia, anorexia, dehydration, decreased appetite, hypokalaemia, insomnia, depression, anxiety, neuropathy (including peripheral/poly/motor/sensory), hypo/paraesthesia, headache, dysgeusia, dizziness, ataxia, sensory disturbance, somnolence, vertigo, tachycardia, arrhythmia, supraventricular tachycardia, flushing, hot flushes, hypertension, lymphedema, interstitial pneumonitis, dyspnoea, epistaxis, pharyngolaryngeal pain, cough, rhinitis, rhinorrhea, nausea, diarrhoea, vomiting, constipation, stomatitis, abdominal pain/distension, dyspepsia, GERD, alopecia, rash, nail disorder, pruritus, dry skin, erythema, nail pigmentation/dyscolouration, skin hyperpigmentation, onycholysis, nail changes, arthralgia, myalgia, fatigue, asthenia, pyrexia, peripheral oedema, mucosal inflammation, pain, rigors, oedema, weakness, decreased performance status, chest pain, influenza-like illness, malaise, lethargy, hyperpyrexia, decreased weight, increased ALT/AST, decreased haematocrit, decreased RBCs count, increased body temperature, increased gamma-glutamyltransferase, increased blood alkaline phosphatase, cystoid macular oedema, palmar-plantar erythrodysesthesiae (previously capecitabine exposure).

MARKETED BY:



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(Additional information is available on request)