

## NAB TORTAXEL™ 100

**To be sold by retail on prescription of an Oncologist/Cancer Hospital/ Institution only**

Abbreviated Prescribing information for NAB TORTAXEL™ 100 [Paclitaxel Protein Bound Particles for Injectable Suspension 100 mg]

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**MECHANISM OF ACTION:** Paclitaxel protein-bound particle for injectable suspension is an antimicrotubular agent that promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions.

**INDICATIONS:** *Metastatic Breast Cancer:* It is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. *Non-Small cell Lung Cancer:* It is indicated for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. *Adenocarcinoma of the Pancreas:* It is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

**DOSAGE AND ADMINISTRATION:** After failure of combination chemotherapy for metastatic breast cancer or relapse within 6 months of adjuvant chemotherapy, the recommended regimen for Paclitaxel protein-bound particles for injectable suspension is 260 mg/m<sup>2</sup> administered intravenously over 30 minutes every 3 weeks. Patients who experience severe neutropenia (neutrophil < 500 cells/mm<sup>3</sup> for a week or longer) or severe sensory neuropathy during Paclitaxel protein-bound particles for injectable suspension therapy should have dosage reduced to 220 mg/m<sup>2</sup> for subsequent courses of Paclitaxel. A Paclitaxel protein-bound particle for injectable suspension is supplied as a sterile lyophilized powder for reconstitution before use. **AVOID ERRORS, READ ENTIRE PREPARATION INSTRUCTIONS PRIOR TO RECONSTITUTION.** Aseptically, reconstitute each vial by injecting 20 mL of 0.9% Sodium Chloride Injection, I.P. Slowly inject the 20 mL of 0.9% Sodium Chloride Injection, I.P., 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, I.P., directly onto the lyophilized cake as this will result in 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. Avoid generation of foam. If foaming or clumping occurs, stand solution for at least 15 minutes until foam subsides.

**CONTRAINDICATION:** Paclitaxel protein-bound particles for injectable suspension should not be used in patients who have baseline neutrophil counts of < 1,500 cells/mm<sup>3</sup>.

**WARNINGS & PRECAUTIONS:** Primarily neutropenia is dose dependent and a dose limiting toxicity. Paclitaxel protein-bound particles for injectable suspension should not be administered to patients with baseline neutrophil counts of < 1,500 cells/mm<sup>3</sup>. Pregnancy Category D- If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment. To monitor the occurrence of myelotoxicity, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving Paclitaxel. In the case of severe neutropenia (<500 cells/mm<sup>3</sup> for seven days or more) during a course of Paclitaxel therapy, a dose reduction for subsequent courses of therapy is recommended. Sensory neuropathy occurs frequently with Paclitaxel. If grade 3 sensory neuropathy develops, treatment should be withheld until resolution to grade

1 or 2 followed by a dose reduction for all subsequent courses. Administration of Paclitaxel in patients with hepatic impairment should be performed with caution. The starting dose should be reduced for patients with moderate and severe hepatic impairment. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, it is recommended that nursing be discontinued when receiving Paclitaxel therapy.

**DRUG INTERACTIONS:** No drug interaction studies have been conducted with Paclitaxel Protein bound Particles for Injectable Suspension. In the absence of formal clinical drug interaction studies, caution should be exercised when administering Paclitaxel concomitantly with medicines known to inhibit (e.g. Ketoconazole and other Imidazole antifungals, erythromycin, fluoxetine, gemfibrozil, cimetidine, ritonavir, saquinavir, indinavir, and nelfinavir) or induce (e.g. rifamycin, carbamazepine, Phenytoin, efavirenz, nevirapine) either CYP2C8 or CYP3A4.

**ADVERSE REACTIONS:** Neutropenia, thrombocytopenia, anemia, hypersensitivity reaction, hypotension, bradycardia, severe cardiovascular events, abnormal ECG, cough, dyspnea, chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, hypertension, cerebrovascular attacks (strokes), transient ischemic attacks, interstitial pneumonia, lung fibrosis, creatinine elevation, cardiac ischemia/infarction, thrombosis/embolism, alopecia, and nail changes (changes in pigmentation or discoloration of nail bed).

**MARKETED BY:**

**TORRENT**  
PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)