

FIRST TIME GENERIC APPROVAL

Brand Name	Abraxane®
Generic Name	paclitaxel-protein bound
Drug Manufacturer	Apotex Corp.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

August 25, 2020

LAUNCH DATE

April 12, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Type 5 - New Formulation or New Manufacturer, New Drug Application (NDA): 021660

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Paclitaxel protein-bound particles for injectable suspension is indicated for the treatment of metastatic breast cancer, non-small cell lung cancer and adenocarcinoma of the pancreas.

MECHANISMS OF ACTION

paclitaxel-protein bound is a microtubule inhibitor 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. Paclitaxel induces abnormal arrays or “bundles” of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

DOSE FORM AND STRENGTH

Injectable Suspension (Albumin-Bound), lyophilized powder for reconstitution, 100 mg/vial.

DOSE & ADMINISTRATION

Breast cancer, metastatic: IV: 260 mg/m² every 3 weeks

Non–small cell lung cancer, locally advanced or metastatic: IV: 100 mg/m² on days 1, 8, and 15 of each 21-day cycle

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Pancreatic adenocarcinoma, metastatic: IV: 125 mg/m² on days 1, 8, and 15 of a 28-day cycle (in combination with gemcitabine).

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