170x230 (front-back)

Paclitaxel (protein-bound particle) for Injectable Suspension 100mg/vial

ABRAACE™
Injection

Each vial contains :

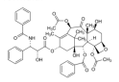
Paclitaxel	IP	100mg
Human Albumin (approximately)	IP	900mg
Excipients		q.s.

DESCRIPTION

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is paclitaxel formulated as albumin-bound nanoparticles with a mean particle size of approximately 130 nanometers. Paclitaxel exists in the particles in a noncrystalline, amorphous state. Paclitaxel is a microtubule inhibitor.

The chemical name for paclitaxel is 5β,20-Epoxy-1,2α,4,7β,10β,13α-hexahydroxytax-11-en-9-one 4,10-diacetate 2-benzoate 13-ester with (2R,3S)-N-benzoyl-3phenylisoserine.

The empirical formula is $C_{47}H_{51}NO_{14}$ and the molecular weight is 853.91. Paclitaxel has the following structural formula:



CLINICAL PHARMACOLOGY

Mechanism of Action

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin 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.

Pharmacokinetics

The pharmacokinetics of total paclitaxel following 30 and 180-minute infusions of protein bound paclitaxel at dose levels of 80 to 375 mg/m^2 (0.31 to 1.15 times the maximum approved recommended dosage) were determined in clinical studies. Dose levels of mg/m^2 refer to mg of paclitaxel in protein bound paclitaxel. Following intravenous administration of protein bound paclitaxel to patients with solid tumors, paclitaxel plasma concentrations declined in a biphasic manner, the initial rapid decline representing distribution to the peripheral compartment and the slower second phase representing drug elimination.

Following protein bound paclitaxel infusion, paclitaxel exhibited linear drug exposure (AUC) across clinical doses ranging from 80 to 300 mg/m^2 (0.31 to 1.15 times the maximum approved recommended dosage). The pharmacokinetics of paclitaxel in protein bound paclitaxel were independent of the duration of intravenous administration. The pharmacokinetic data of 260 mg/m^2 protein bound paclitaxel administered over a 30-minute infusion was compared to the pharmacokinetics of 175 mg/m^2 paclitaxel injection over a 3 hour infusion. Clearance was larger (43%) and the volume of distribution was higher (53%) for protein bound paclitaxel than for paclitaxel injection. There were no differences in terminal half-lives.

Distribution

Following protein bound paclitaxel administration to patients with solid tumors, paclitaxel is evenly distributed into blood cells and plasma and is highly bound to plasma proteins (94%). The total volume of distribution is approximately 1741 L; the large volume of distribution indicates extensive extravascular distribution and/or tissue binding of paclitaxel.

In a within-patient comparison study, the fraction of unbound paclitaxel in plasma was significantly higher with protein bound paclitaxel (6.2%) than with solvent-based paclitaxel (2.3%). This contributes to significantly higher exposure to unbound paclitaxel with protein bound paclitaxel compared withsolvent -based paclitaxel, when the total exposure is comparable. In vitro studies of binding to human serum proteins, using paclitaxel concentrations ranging from 0.1 to 50 µg/mL, indicated that the presence of cimetidine, ranitidine, dexamethasone, or diphenhydramine did not affect protein binding of paclitaxel.

Elimination

At the clinical dose range of 80 to 300 mg/m^2 (0.31 to 1.15 times the maximum approved recommended dosage), the mean total clearance of paclitaxel ranges from 13 to 30 L/h/m^2 and the mean terminal half-life ranges from 13 to 27 hours.

Metabolism

In vitro studies with human liver microsomes and tissue slices showed that paclitaxel in protein bound paclitaxel was metabolized primarily to 6α-hydroxypaclitaxel by CYP2C8; and to two minor metabolites, 3'-p-hydroxypaclitaxel and 6α, 3'-p-dihydroxypaclitaxel, by CYP3A4. In vitro, the metabolism of paclitaxel to 6α-hydroxypaclitaxel was inhibited by a number of agents (ketoconazole, verapamil, diazepam, quinidine, dexamethasone, cyclosporin, teniposide, etoposide, and vincristine), but the concentrations used exceeded those found in vivo following normal therapeutic doses. Testosterone, 17α-ethinyl estradiol, retinoic acid, and quercetin, a specific inhibitor of CYP2C8, also inhibited the formation of 6α-hydroxypaclitaxel in vitro. The pharmacokinetics of paclitaxel may also be altered in vivo as a result of interactions with compounds that are substrates, inducers, or inhibitors of CYP2C8 and/or CYP3A4.

Excretion

After a 30-minute infusion of 260 mg/m^2 doses of protein bound paclitaxel, the mean values for cumulative urinary recovery of unchanged drug (4%) indicated extensive non renal clearance. Less than 1% of the total administered dose was excreted in urine as the metabolites 6α-hydroxypaclitaxel and 3'-p-hydroxypaclitaxel. Fecal excretion was approximately 20% of the total dose administered.

INDICATIONS AND USAGE

Paclitaxel Protein-Bound Particles for Injectable suspension is indicated for the treatment of:

• Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

• Locally advanced or metastatic non-small cell lung cancer (NSCLC), as first-line treatment incombinatio n with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

• Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

DOSAGE AND ADMINISTRATION

Important Administration Instructions

DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS.

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) has different dosage and administration instructions from other paclitaxel products.

Closely monitor the infusion site for extravasation or drug infiltration during administration.

Limiting the infusion of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) to 30 minutes may reduce the risk of infusion-related reactions.

Consider premedication in patients who have had prior hypersensitivity reactions to Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound).

Do not re-challenge patients who experience a severe hypersensitivity reaction to Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound).

Recommended Dosage for Metastatic Breast Cancer

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 (Albumin-Bound) is 260 mg/m^2 administered intravenously over 30 minutes every 3 weeks.

Recommended Dosage for Non-Small Cell Lung Cancer

The recommended dose of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is 100 mg/m^2 administered as an intravenous infusion over 30 minutes on Days 1, 8, and 15 of each 21-day cycle.

Administer carboplatin on Day 1 of each 21-day cycle immediately after Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound).

Recommended Dosage for Adenocarcinoma of the Pancreas

The recommended dose of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is 125 mg/m^2 administered as an intravenous infusion over 30-40 minutes on Days 1, 8 and 15 of each 28 day cycle. Administer gemcitabine immediately after Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) on Days 1, 8 and 15 of each 28 day cycle.

Dosage Modifications for Hepatic Impairment

For patients with moderate or severe hepatic impairment, reduce the starting dose of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) as shown in Table 1.

Table 1: Recommendations for Starting Dose in Patients with Moderate and Severe Hepatic Impairment

	AST Levels		Bilirubin Levels	Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) Dose[a]		
				MBC	NSCLC[c]	Adenocarcinoma of Pancreas[c]
Moderate	< 10 x ULN	AND	> 1.5 to ≤ 3 x ULN	200 mg/m^2 [b]	80 mg/m^2 [b]	not recommended
Severe	< 10 x ULN	AND	> 3 to ≤ 5 x ULN	200 mg/m^2 [b]	80 mg/m^2 [b]	not recommended
	> 10 x ULN	OR	> 5 x ULN	not recommended	not recommended	not recommended

AST = Aspartate Aminotransferase; MBC = Metastatic Breast Cancer; NSCLC = Non-Small Cell Lung Cancer; ULN = Upper limit of normal.

a Dosage recommendations are for the first course of therapy. The need for further doseadjustments in subsequent courses should be based on individual tolerance.

b A dose increase to 260 mg/m^2 for patients with metastatic breast cancer or 100 mg/m^2 for patients with non small cell lung cancer in subsequent courses should be considered if the patient tolerates the reduced dose for two cycles.

c Patients with bilirubin levels above the upper limit of normal were excluded from clinical trials for pancreatic or lung cancer.

Preparation for Intravenous Administration

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is a hazardous drug. Follow applicable special handling and disposal procedures. The use of gloves is recommended. If Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) (lyophilized cake or reconstituted suspension) contacts the skin, wash the skin immediately and thoroughly with soap and water. Following topical exposure to paclitaxel, events may include tingling, burning and redness. If Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) contacts mucous membranes, the membranes should be flushed thoroughly with water.

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is supplied as a sterile lyophilized powder for reconstitution before use. Read the entire preparation instructions prior to reconstitution.

1. Aseptically, reconstitute each vial by injecting 20 mL of 0.9% Sodium Chloride Injection, IP.
2. 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.

3. DO NOT INJECT the 0.9% Sodium Chloride Injection, IP, directly onto the lyophilized cake as this will result in foaming.
4. 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.
5. 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.
6. 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. The reconstituted suspension should be milky and homogenous without visible particulates. If particulates or settling are visible, the vial should be gently inverted again to ensure complete resuspension prior to use. Discard the reconstituted suspension if precipitates are observed. Discard any unused portion.

Calculate the exact total dosing volume of 5 mg/mL suspension required for the patient and slowly withdraw the dosing volume of the reconstituted suspension from the vial(s) into a syringe:

Dosing volume (mL)=Total dose (mg)/5 (mg/mL).

Inject the appropriate amount of reconstituted Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) into an empty, sterile intravenous bag [plasticized polyvinyl chloride (PVC) containers, PVC or non-PVC type intravenous bag]. The use of specialized DEHP-free solution containers or administration sets is not necessary to prepare or administer Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) infusions. The use of medical devices containing silicone oil as a lubricant (i.e., syringes and intravenous bags) to reconstitute and administer Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) may result in the formation of proteinaceous strands.

Visually inspect the reconstituted Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) suspension in the intravenous bag prior to administration. Discard the reconstituted suspension if proteinaceous strands, particulate matter or discoloration are observed.

CONTRAINDICATIONS

• Neutrophil counts of < 1,500 cells/mm^3.

• Severe hypersensitivity reactions to Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound).

WARNINGS AND PRECAUTIONS

Severe Myelosuppression

Severe myelosuppression (primarily neutropenia) is dose-dependent and a dose-limiting toxicity of protein bound paclitaxel. In clinical studies, Grade 3-4 neutropenia occurred in 34% of patients with metastatic breast cancer (MBC), 47% of patients with non-small cell lung cancer (NSCLC), and 38% of patients with pancreatic cancer. Monitor for severe neutropenia and thrombocytopenia by performing complete blood cell counts frequently, including prior to dosing on Day 1 (for MBC) and Days 1, 8, and 15 (for NSCLC and for pancreatic cancer). Do not administer Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) to patients with baseline absolute neutrophil counts (ANC) of less than 1,500 cells/mm^3. In the case of severe neutropenia (<500 cells/mm^3) for seven days or more) during a course of Paclitaxel Protein -Bound Particles for InjectableSuspension (Albumin-Bound) therapy, reduce the dose of Paclitaxel Protein -Bound Particles for Injectable Suspension (Albumin-Bound) in subsequent courses in patients with either MBC or NSCLC.

In patients with MBC, resume treatment with every-3-week cycles of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) after ANCreco vers to a level >1,500 cells/mm^3 and platelets recover to a level >100,000cells/mm ^{3}. In patients with NSCLC, resume treatment if recommended at permanently reduced doses for both weekly Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) and every-3-week carboplatin after ANC recovers to at least 1500 cells/mm^3 and platelet count of at least 100,000 cells/mm^3 on Day 1 or to an ANC of at least 500 cells/mm^3 and platelet count of at least 50,000 cells/mm^3 on Days 8 or 15 of the cycle. In patients with adenocarcinoma of the pancreas, withhold PaclitaxelProtein -Bound Particles for Injectable Suspension (Albumin Bound) and gemcitabine if the ANC is less than 500 cells/mm^3 or platelets are less than 50,000 cells/mm^3 and delay initiation of the next cycleif the ANC is less than 1500 cells/mm^3 or platelet count is less than100,000 cells/mm ^{3} on Day 1 of the cycle. Resume treatment with appropriate dose reduction if recommended.

Severe Neuropathy

Sensory neuropathy is dose- and schedule-dependent. If ≥ Grade 3 sensory neuropathy develops, withhold Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) treatment until resolution to Grade 1 or 2 for metastatic breast cancer or until resolution to ≤ Grade 1 for NSCLC and pancreatic cancer followed by a dose reduction for all subsequent courses of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound).

Sepsis

Sepsis occurred in 5% of patients with or without neutropenia who received protein bound paclitaxel in combination with gemcitabine. Biliary obstructionor presence of biliary stent were risk factors for severe or fatal sepsis.

If a patient becomes febrile (regardless of ANC) initiate treatment withbroad spectrum antibiotics. For febrile neutropenia, interrupt Paclitaxel Protein -Bound Particles for Injectable Suspension (Albumin Bound) and gemcitabine until fever resolves and ANC ≥ 1500, then resume treatment at reduced dose levels.

Pneumonitis

Pneumonitis, including some cases that were fatal, occurred in 4% of patients receiving protein bound paclitaxel in combination with gemcitabine.

Monitor patients for signs and symptoms of pneumonitis and interrupt Paclitaxel Protein -Bound Particles for Injectable Suspension (Albumin-Bound) and gemcitabine during evaluation of suspected pneumonitis. After ruling out infectious etiology and upon making a diagnosis of pneumonitis, permanently discontinue treatment with Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) and gemcitabine.

Severe Hypersensitivity

Severe and sometimes fatal hypersensitivity reactions, includinganaphylactic reactions, have been reportedDo not rechallenge patients who experience a severe hypersensitivity reaction to Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) with this drug.

Cross-hypersensitivity between protein bound paclitaxel and other taxane products has been reported and may include severe reactions such as anaphylaxis. Closely monitor patients with a previous history of hypersensitivity to other taxanes during initiation of Paclitaxel Protein Bound Particles for Injectable Suspension (Albumin-Bound) therapy.

Use in Patients with Hepatic Impairment

The exposure and toxicity of paclitaxel can be increased in patients with hepatic impairment. Closely monitor patients with hepatic impairment for severe myelosuppression Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is not recommended in patients who have total bilirubin >5 x ULN or AST>10xULN.

In addition, Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) is not recommended in patients with metastatic adenocarcinoma of the pancreas who have moderate to severe hepatic impairment (total bilirubin >1.5 x ULN and AST ≤10 x ULN). Reduce the starting dose for patients with moderate or severe hepatic impairment.

Albumin (Human)

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) contains albumin (human), a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries a remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Embryo-Fetal Toxicity

Based on mechanism of action and findings in animals, Paclitaxel Protein Bound Particles for Injectable Suspension (Albumin-Bound) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of protein bound paclitaxel to rats during pregnancy at doses lower than the maximum recommended human dose, based on body surface area, caused embryo-fetal toxicities, including intrauterine mortality, increased resorptions, reduced numbers of live fetuses, and malformations. Advise females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception and avoid becoming pregnant during treatment with Paclitaxel -Protein Bound Particles for Injectable Suspension (Albumin-Bound) and for at least six months after the last dose.

Based on findings from genetic toxicity and animal reproduction studies, advise male patients with female partners of reproductive potential to use effective contraception and avoid fathering a child during treatment with Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) and for at least three months after the last dose.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most common adverse reactions (≥20%) with single-agent use of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) in metastatic breast cancer are alopecia, neutropenia, sensory neuropathy, abnormal ECG, fatigue/asthenia, myalgia/arthralgia, AST elevation, alkaline phosphatase elevation, anemia, nausea, infections, and diarrhea.

The most common adverse reactions (≥20%) of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) incombination with carboplatin for non -small cell lung cancer are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue.The most common serious adverse reactions of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) in combination with carboplatin for non-small cell lung cancer are anemia (4%) and pneumonia (3%). The most common adverse reactions resulting in permanent discontinuation of Paclitaxel Protein -Bound Particles for Injectable Suspension (Albumin-Bound) are neutropenia (3%), thrombocytopenia (3%), and peripheral neuropathy (1%).

The most common adverse reactions resulting in dose reduction of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) are neutropenia (24%), thrombocytopenia (13%), and anemia (6%). The most common adverse reactions leading to withholding or delay in Paclitaxel Protein-Bound Particles forInjectable Suspension (Albumin-Bound) dosing are neutropenia (41%), thrombocytopenia (30%), and anemia (16%) .

In a randomized open-label trial of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) in combination with gemcitabine for pancreatic adenocarcinoma.

The most common (≥ 20%) selected (with a ≥ 5% higher incidence) adverse reactions of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) are neutropenia, fatigue, peripheral neuropathy, nausea, alopecia, peripheral edema, diarrhea, pyrexia, vomiting, decreased appetite, rash, and dehydration.

The most common serious adverse reactions of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) (with a ≥1% higher incidence) are pyrexia (6%), dehydration (5%), pneumonia (4%), and vomiting (4%). The most common adverse reactions resulting in permanent discontinuation of Paclitaxel Protein -Bound Particles for Injectable Suspension (Albumin-Bound) are peripheral neuropathy (8%), fatigue (4%), and thrombocytopenia (2%). The most common adverse reactions resulting in dose reduction of Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) are neutropenia (10%) and peripheral neuropathy (6%).

The most common adverse reactions leading to withholding or delay in Paclitaxel Protein-Bound Particlesfor Injectable Suspension (Albumin-Bound) dosing are neutropenia (16%) , thrombocytopenia (12%), fatigue (8%), peripheral neuropathy (15%), anemia (5%), and diarrhea (5%).

DRUG INTERACTIONS

The metabolism of paclitaxel is catalyzed by CYP2C8 and CYP3A4. Caution should be exercised when administering Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) concomitantly with medicines known to inhibit or induce either CYP2C8 or CYP3A4.

PREGNANCY

Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) can cause fetal harm when administered to a pregnant woman. There are no available human data on Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) use in pregnant women to inform the drug-associated risk.

In animal reproduction studies, administration of paclitaxel formulated as albumin-bound particles topregnant rats during the period of organogenesis resulted in embryo-fetal toxicity at doses approximately 2% of the daily maximum recommended human dose on a mg/m^2 basis. Advise females of reproductive potential of the potential risk to a fetus.

LACTATION

There are no data on the presence of paclitaxel in human milk, or its effect on the breastfed child or on milk production. In animal studies, paclitaxel and/or its metabolites were excreted into the milk of lactating rats. Because of the potential for serious adverse reactions in a breastfed child from Paclitaxel Protein Bound Particles for Injectable Suspension (Albumin Bound), advise lactating women not to breastfeed during treatment with Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) and for two weeks after the last dose.

PEDIATRIC USE

Safety and effectiveness in pediatric patients have not been established. Pharmacokinetics, safety, and antitumor activity of protein bound paclitaxel were assessed in an open-label, doseescalation, dose expansion study (NCT01962103) in 96 pediatric patients aged 1.4 to < 17 years with recurrent or refractory pediatric solid tumors. The maximum tolerated dose (MTD) normalized for body surface area (BSA) was lower in pediatric patients compared to adults. No new safety signals were observed in pediatric patients across these studies.

Paclitaxel protein-bound exposures normalized by dose were higher in 96 pediatric patients (aged 1.4 to < 17 years) as compared to those in adults.

GERIATRIC USE

Of the 229 patients in the randomized study who received protein bound paclitaxel for the treatment of metastatic breast cancer, 13% were at least 65 years of age and <2% were 75 years or older. This study of protein bound paclitaxel did not include a sufficient number of patients with metastatic breast cancer who were 65 years and older to determine whether they respond differently from younger patients.

A subsequent pooled analysis was conducted in 981 patients receiving protein bound paclitaxel monotherapy for metastatic breast cancer, of which 15% were 65 years of age or older and 2% were 75 years of age or older. A higher incidence of epistaxis, diarrhea, dehydration, fatigue, and peripheral edema was found in patients 65 years of age or older.

RENAL IMPAIRMENT

No adjustment of the starting Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) dose is required for patients with mild to moderate renal impairment (estimated creatinine clearance 30 to <90 mL/min). There are insufficient data to permit dosage recommendations in patients with severe renal impairment or end stage renal disease (estimated creatinine clearance <30 mL/min).

OVERDOSAGE

There is no known antidote for Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin-Bound) overdosage. The primary anticipated complications of overdosage would consist of bone marrow suppression, sensory neurotoxicity and mucositis.

STABILITY OF RECONSTITUTED SUSPENSION IN THE VIAL

Reconstituted Paclitaxel Protein-Bound Particles for Injectable Suspension (Albumin Bound) in the vial should be used immediately, but may be refrigerated at 2°C to 8°C (36°F to 46°F) for a maximum of 24 hours if necessary. If not used immediately, each vial of reconstituted suspension should be replaced in the original carton to protect it from light. Discard any unused portion.

Storage Condition :

Storage: Store vial in its original carton at controlled room temperature between 20°C and 25°C.

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