



PACLITAXEL Injection, USP

SAGENT offers injectables excellence in oncology

- Available in:
 - 30 mg per 5 mL multi-dose vials
 - 100 mg per 16.7 mL multi-dose vials
 - 300 mg per 50 mL multi-dose vials
- LATEX-FREE
- Preservative-free
- Discover **PreventIV Measures™** packaging features:
 - Easy-to-read drug name and dosage strength
 - Bar codes included on the vials and cartons for ease of scanning
 - Unique label design
 - Yellow and black cytotoxic warning flag designed to caution healthcare workers who handle the product

Enhanced packaging and labeling designed to promote safety and help reduce medication errors



Please see full prescribing information for PACLITAXEL Injection, USP, enclosed.



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PACLITAXEL Injection, USP



Innovator Product Name: TAXOL® (TAXOL is a registered trademark of Bristol-Myers Squibb Company.)

NDC Number	Description	Strength	Fill Volume	Concentration	Closure	Unit of Sale	Bar Coded
25021-213-05	Glass Vial	30 mg	5 mL	6 mg per mL	20 mm	1 Vial	✓
25021-213-17	Glass Vial	100 mg	16.7 mL	6 mg per mL	20 mm	1 Vial	✓
25021-213-50	Glass Vial	300 mg	50 mL	6 mg per mL	20 mm	1 Vial	✓

This SAGENT product meets stringent FDA requirements and is AP rated, LATEX-FREE and preservative-free.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

Listening. Responding. Delivering. That's Injectables Excellence.™ That's SAGENT Pharmaceuticals.

PACLITAXEL Injection, USP

INDICATIONS AND USAGE

- Paclitaxel Injection, USP is indicated as first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Paclitaxel Injection, USP is indicated in combination with cisplatin.
- Paclitaxel Injection, USP is indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy.
- Paclitaxel Injection, USP is indicated for the treatment of 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.
- Paclitaxel Injection, USP, in combination with cisplatin, is indicated for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.
- Paclitaxel Injection, USP is indicated for the second-line treatment of AIDS-related Kaposi's sarcoma

IMPORTANT SAFETY INFORMATION

WARNING

Paclitaxel Injection, USP should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred in 2 to 4% of patients receiving paclitaxel in clinical trials. Fatal reactions have occurred in patients with AIDS-related Kaposi's sarcoma if the baseline neutrophil count is less than 1000 cells/mm³. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving Paclitaxel Injection, USP.

Paclitaxel Injection, USP therapy should not be given to patients with solid tumors who have baseline neutrophil counts of less than 1500 cells/mm³ and should not be given to patients with AIDS-related Kaposi's sarcoma if the baseline neutrophil count is less than 1000 cells/mm³. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving Paclitaxel Injection, USP.

CONTRAINDICATIONS

- Paclitaxel Injection, USP is contraindicated in patients who have a history of hypersensitivity reactions to Paclitaxel Injection, USP or other drugs formulated in Cremophor® EL (polyoxyethylated castor oil).
- Paclitaxel Injection, USP should not be used in patients with solid tumors who have baseline neutrophil counts of <1500 cells/mm³ or in patients with AIDS-related Kaposi's sarcoma with baseline neutrophil counts of <1000 cells/mm³.

WARNINGS

- Anaphylaxis and severe hypersensitivity reactions characterized by dyspnea and hypotension requiring treatment, angioedema, and generalized urticaria have occurred in 2 to 4% of patients receiving paclitaxel in clinical trials. Fatal reactions have occurred in patients despite premedication. All patients should be pretreated with corticosteroids, diphenhydramine, and H₂ antagonists.
- Bone marrow suppression (primarily neutropenia) is dose-dependent and is the dose-limiting toxicity. Neutrophil nadirs occurred at a median of 11 days. Paclitaxel Injection, USP should not be administered to

patients with baseline neutrophil counts of less than 1500 cells/mm³ (<1000 cells/mm³ for patients with KS). Frequent monitoring of blood counts should be instituted during Paclitaxel Injection, USP treatment.

- Severe conduction abnormalities have been documented in <1% of patients during paclitaxel therapy and in some cases requiring pacemaker placement.
- Paclitaxel can cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in pregnant women.

PRECAUTIONS

- Contact of the undiluted concentrate with plasticized polyvinyl chloride (PVC) equipment or devices used to prepare solutions for infusion is not recommended.
- Paclitaxel Injection, USP should be administered through an in-line filter with a microporous membrane not greater than 0.22 microns.
- The metabolism of paclitaxel is catalyzed by cytochrome P450 isoenzymes CYP2C8 and CYP3A4. Caution should be exercised when paclitaxel is concomitantly administered with known substrates, inhibitors, and inducers of CYP2C8 and CYP3A4.
- Hypotension, bradycardia, and hypertension have been observed during administration of paclitaxel, but generally do not require treatment.
- Although the occurrence of peripheral neuropathy is frequent, the development of severe symptomatology is unusual and requires a dose reduction of 20% for all subsequent courses of Paclitaxel Injection, USP.
- There is limited evidence that the myelotoxicity of paclitaxel may be exacerbated in patients with serum total bilirubin >2 times ULN.
- Injection site reactions, including reactions secondary to extravasation, were usually mild and consisted of erythema, tenderness, skin discoloration, or swelling at the injection site. More severe events such as phlebitis, cellulitis, induration, skin exfoliation, necrosis, and fibrosis have been reported.
- The carcinogenic potential of paclitaxel has not been studied.
- It is not known whether the drug is excreted in human milk.
- The safety and effectiveness of paclitaxel in pediatric patients have not been established.
- In most studies, severe myelosuppression was more frequent in elderly patients; in some studies, severe neuropathy was more common in elderly patients.

ADVERSE REACTIONS

The most common adverse events in patients treated with paclitaxel, as a single-agent therapy or in combination therapy, are neutropenia, leukopenia, thrombocytopenia, anemia, infections, febrile neutropenia, hypersensitivity reaction, peripheral neuropathy, nausea and vomiting, diarrhea, mucositis, myalgia/arthralgia, alopecia, hypotension and bradycardia.

OVERDOSAGE

There is no known antidote for paclitaxel overdose. The primary anticipated complications of overdose would consist of bone marrow suppression, peripheral neurotoxicity, and mucositis. Overdose in pediatric patients may be associated with acute ethanol toxicity.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for PACLITAXEL Injection, USP.

LATEX-FREE = There is no natural rubber latex in the vial container closure or label adhesive in this SAGENT product.

TAXOL is a registered trademark of Bristol-Myers Squibb Company. All other trademarks used herein are the property of Sagent Pharmaceuticals, Inc.

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