



Paclitaxel Injection

(pak'' li tax' el)

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IMPORTANT WARNING:

Paclitaxel injection must be given in a hospital or medical facility under the supervision of a doctor who is experienced in giving chemotherapy medications for cancer.

Paclitaxel may cause a large decrease in the number of white blood cells (a type of blood cell that is needed to fight infection) in your blood. This increases the risk that you will develop a serious infection. You should not receive paclitaxel if you already have a low number of white blood cells. Your doctor will order laboratory tests before and during your treatment to check the number of white blood cells in your blood. Your doctor will delay or interrupt your treatment if the number of white blood cells is too low. Call your doctor immediately if you develop a temperature greater than 100.4° F, a sore throat, cough, chills, or other signs of infection during your treatment with paclitaxel.

Paclitaxel is manufactured with additional ingredients to allow the medication to reach parts of the body where it is needed. One form of paclitaxel (Abraxane) is manufactured with human albumin, and the other form of paclitaxel (Taxol) is manufactured with a solvent called Cremophor EL (polyoxyethylated castor oil). There are important differences between the two forms of paclitaxel, so these products should not be substituted for each other.

If you are using the form of paclitaxel that is manufactured with Cremophor EL, you may experience a serious or life-threatening allergic reaction. You will receive certain medications to help prevent an allergic reaction before you receive each dose of paclitaxel. Tell your doctor if you experience any of the following symptoms of an allergic reaction: rash; hives; itching; swelling of the eyes, face, throat, lips, tongue, hands, arms, feet, or ankles; difficulty breathing or swallowing; dizziness; or fainting.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to paclitaxel.

Talk to your doctor about the risks of using paclitaxel.

Why is this medication prescribed?

Paclitaxel manufactured with human albumin is used to treat breast cancer that has not improved or that has come back after treatment with other medications. Paclitaxel manufactured with Cremophor EL is used to treat ovarian cancer (cancer that begins in the female reproductive organs where eggs are formed), breast cancer, and lung cancer. Paclitaxel with Cremophor EL is also used to treat Kaposi's sarcoma (a type of cancer that causes patches of abnormal tissue to grow under the skin) in people who have acquired immunodeficiency syndrome (AIDS). Paclitaxel is in a class of medications called antimicrotubule agents. It works by stopping the growth and spread of cancer cells.

How should this medicine be used?

Paclitaxel comes as a liquid to be given intravenously (into a vein) by a doctor or nurse in a hospital or clinic. It is usually given once every 3 weeks. When paclitaxel manufactured with Cremophor EL is used to treat Kaposi's sarcoma, it may be given once every 2 or 3 weeks.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

Paclitaxel is also sometimes used to treat cancer of the head and neck, esophagus (tube that connects the mouth and stomach), bladder, endometrium (lining of the uterus), and cervix (opening of the uterus). Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using paclitaxel,

- tell your doctor and pharmacist if you are allergic to paclitaxel, any other medications, human albumin, Cremophor EL, or medications that contain Cremophor EL such as cyclosporine injection (Sandimmune) and teniposide (Vumon). Ask your doctor or pharmacist if you do not know if a medication that you are allergic to contains human albumin or Cremophor EL.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: amiodarone (Cordarone, Pacerone); aripiprazole (Abilify); buspirone (Buspar); certain antibiotics such as clarithromycin (Biaxin), erythromycin (E.E.S., E-Mycin), and telithromycin (Ketek); certain benzodiazepines such as alprazolam (Xanax), diazepam (Valium), midazolam, and triazolam (Halcion); certain antifungals such as itraconazole (Sporanox) and ketoconazole (Nizoral); certain calcium channel blockers such as amlodipine (Norvasc, in Azor, in Caduet, in Lotrel), diltiazem (Cardizem, Dilacor, Tiazac), nifedipine (Adalat, Procardia), nisoldipine (Sular), and verapamil (Calan, Tarka, Verelan); certain cholesterol-lowering medications (statins) such as atorvastatin (Lipitor), lovastatin (Mevacor), and simvastatin (Zocor); cimetidine (Tagamet); cisplatin (Platinol); cyclosporine (Gengraf, Neoral, Sandimmune); doxorubicin (Doxil); fluvoxamine; gemfibrozil (Lopid); imatinib (Gleevec); methadone (Dolophine); montelukast (Singulair); nefazodone; pimozide (Orap); protease inhibitors used to treat human immunodeficiency virus (HIV) such as indinavir (Crixivan), ritonavir (Norvir, in Kaletra), nelfinavir (Viracept), and saquinavir (Invirase); quinidine; quinine (Qualaquin); sildenafil (Viagra); tacrolimus (Prograf); tamoxifen (Nolvadex); trazodone; and vincristine. Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with paclitaxel, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you have or have ever had liver or heart disease.
- tell your doctor if you are pregnant or plan to become pregnant, or if you plan to father a child. You or your partner should not become pregnant while you are using paclitaxel. You should use birth control to prevent pregnancy in yourself or your

partner during your treatment with paclitaxel. Talk to your doctor about birth control methods that will work for you. If you or your partner become pregnant while using paclitaxel, call your doctor. Paclitaxel may harm the fetus.

- do not breast-feed while you are using paclitaxel.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using paclitaxel.
- if you are using paclitaxel manufactured with Cremophor EL, you should know that the medication contains alcohol. Do not drive a car or operate machinery until you know how this medication affects you. Talk to your doctor about the safe use of alcoholic beverages or medications that may affect your thinking or judgment during your treatment.
- talk to your doctor before you receive any vaccinations during your treatment with paclitaxel.
- you should know that paclitaxel may make it more difficult for your body to fight infection. Wash your hands often and avoid crowds and people who are sick during your treatment with paclitaxel.
- you should know that paclitaxel may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while using this medicine.

What should I do if I forget a dose?

Call your doctor right away if you are unable to keep an appointment to receive a dose of paclitaxel.

What side effects can this medication cause?

Paclitaxel may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- pain, redness, swelling, or sores in the place where the medication was injected
- weakness
- nausea
- vomiting
- diarrhea
- sores in the mouth
- hair loss

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- numbness, burning, or tingling in the hands or feet
- pale skin
- excessive tiredness
- unusual bruising or bleeding
- chest pain
- irregular heartbeat
- blistering or peeling skin

Paclitaxel may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include:

- pale skin
- shortness of breath
- excessive tiredness
- sore throat, fever, chills, and other signs of infection
- unusual bruising or bleeding
- numbness, burning, or tingling of the hands and feet
- sores in the mouth

What other information should I know?

Keep all appointments with your doctor.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Abraxane®
- Taxol®

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