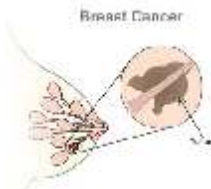
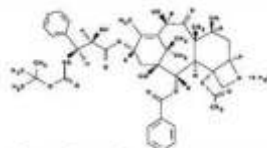


Rx DOCETAXEL

(Docetaxel is a cancer drug that is used for treating breast cancer)



GENERIC NAME: docetaxel

DRUG CLASS AND MECHANISM

Docetaxel is a cancer drug that is used for treating breast cancer. Docetaxel works by attacking cancer cells. Different medications attack cancer cells in different ways. Every cell in your body contains a supporting structure (almost like a skeleton) called the microtubular network. If this "skeleton" is changed or damaged, the cell can't grow or reproduce. Taxotere makes the "skeleton" in cancer cells unnaturally stiff, so that these cells can no longer grow.

GENERIC AVAILABLE: No

PRESCRIPTION: Yes

PREPARATIONS: Concentrate liquid for intravenous injection. The concentrate requires dilution prior to administration

PRESCRIBED FOR

Docetaxel (Taxotere) for Injection Concentrate is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy. Docetaxel (Taxotere) has recently been approved for the 2nd-line treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior platinum-based chemotherapy.

DOSING

Docetaxel (Taxotere) for Injection Concentrate is given intravenously (by a needle that is put into your vein) every 3 weeks. Each treatment takes about 1 hour. Again, every patient is different. Your doctor will determine what dose of Taxotere is right for you and how often you should receive it.

DRUG INTERACTIONS

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Docetaxel should not be used with live vaccines because very serious interactions may occur. Tell your doctor if you have just received a live vaccine or plan to get one. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: other drugs for cancer, drugs affecting liver enzymes that remove docetaxel from your body (such as azole antifungals-including itraconazole, aprepitant, macrolide antibiotics-including erythromycin, cimetidine, rifamycins-including rifabutin, St John's wort, certain anti-seizure medicines-including carbamazepine).

USES

This medication is used to treat certain types of cancer (e.g., breast, lung, and prostate cancer). Docetaxel is a member of a family of drugs called taxanes. This drug works by slowing cell growth.

HOW TO USE

This medication is given by vein (intravenously-IV), generally over 1 hour every 3 weeks as directed by your doctor. The dosage and frequency is based on your medical condition and response to therapy. Your doctor may prescribe pre-medications (e.g., corticosteroids such as dexamethasone) to prevent side effects like swelling (fluid retention/edema) and allergic reactions. These are generally started 1 day before treatment and continued for a total of 3 days. Carefully follow your doctors orders to prepare for your treatment. Follow all instructions for proper mixing and dilution with correct IV fluids. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. The final solution should be mixed well by gentle rotation of the IV bag, but never shaken. Read the Patient Information Leaflet available from your pharmacist. Consult your doctor, nurse or pharmacist if you have any questions.

SIDE EFFECTS

See also Warning section. Pain or swelling at the injection site, nausea, vomiting, diarrhea, excessive tearing, fatigue and loss of appetite may occur. Nausea and vomiting can be severe. In some cases, drug therapy may be necessary to prevent or relieve nausea and vomiting. Not eating before your treatment may help relieve nausea and vomiting. Changes in diet such as eating several small meals or limiting activity may help lessen some of these effects. If these effects persist or worsen, notify your doctor or pharmacist promptly. Temporary hair loss and nail changes may occur. Normal hair growth and nail appearance should return after treatment has ended. Remember that your doctor has prescribed this medication because the

benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: swelling of the hands, unexplainable weight gain, numbness or tingling of the hands or feet, muscle or joint pain, persistent weakness or fatigue, eye pain. Tell your doctor immediately if any of these rare but very serious side effects occur: chest pain, irregular heart beat, severe stomach pain, black or bloody stools, severe headache, decrease in amount of urine. This medication can lower the body's ability to fight an infection. Notify your doctor promptly if you develop any signs of an infection such as fever, chills or persistent sore throat. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

Before receiving docetaxel, tell your doctor or pharmacist if you are allergic to it; or other drugs containing polysorbate 80; or if you have any other allergies. Docetaxel should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: liver problems, lung problems (e.g., pulmonary effusions), heart problems (e.g., congestive heart failure), weak immune system (e.g., neutropenia). Before receiving docetaxel, tell your doctor or pharmacist your medical history, especially of: pregnancy, blood problems (e.g., anemia, thrombocytopenia), blood pressure problems. Do not have immunizations/vaccinations without the consent of your doctor and avoid contact with people who have recently received oral polio vaccine. Use caution with sharp objects like razors or nail cutters and avoid activities such as contact sports to lower the chance of getting cut, bruised or injured. Wash your hands well to prevent the spread of infections. The pre-medications that you take before you take docetaxel may make you dizzy or drowsy. Use caution and limit activities requiring alertness such as driving or using machinery. Limit alcoholic beverages as it may aggravate some of the side effects and make your stomach and intestines more likely to bleed. Caution is advised when using this drug in the elderly because they may be more sensitive to its effects, especially diarrhea, swelling, and mouth sores. This drug is not recommended for use during pregnancy. It may cause fetal harm. Consult your doctor before taking docetaxel and discuss the use of reliable birth control methods during therapy and for 3 months afterwards. If you become pregnant or think you may be pregnant, inform your doctor immediately. It is not known if this drug passes into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

Low White Blood Cell Count

Usually, you will not feel it if you have a low white blood cell count, since there are no specific symptoms associated with this side effect unless an infection develops. Your nurse or doctor will check your blood count if he or she thinks it is necessary. Your white blood cells protect your body against infection. Like many agents used to treat cancer, docetaxel (Taxotere) may cause a temporary drop in the number of white blood cells (a condition known as neutropenia) and may increase the risk of infection. However, most people receiving docetaxel (Taxotere) don't develop infections, even when their white blood cell count is low.

Fever

Fever is one of the most common and earliest signs of infection. If you have a fever over 100°F, make sure to call your doctor or nurse immediately. You should also tell your doctor about other symptoms of infection, such as a sore throat or cough or a burning sensation while urinating.

Allergic Reactions

This type of reaction, which occurs during the infusion of docetaxel (Taxotere), is infrequent. If you feel a warm sensation, difficulty in breathing, or itching during or shortly after your treatment, tell your doctor or nurse immediately. If you have a mild allergic reaction to the first few infusions of docetaxel (Taxotere), such as flushing or a rash, notify the nurse. The doctor will generally stop treatment for a few minutes and then restart the infusion.

Fluid Retention

Fluid retention is a term used to describe an accumulation of fluid in body tissues and/or body cavities. It is important for you to let your doctor or nurse know if you have any signs of fluid retention. Watch for shortness of breath, swelling of your feet or hands, or unexplained weight gain.

In severe cases, shortness of breath may develop due to fluid accumulation in body cavities such as the area surrounding your lungs, the space around your

heart, or in your abdomen. Dexamethasone is used to prevent or reduce fluid retention in patients taking docetaxel (Taxotere). It is important that you take your dexamethasone exactly as your doctor or nurse advises you. If you forget to take your dexamethasone, it is very important that you tell your doctor or nurse before you receive your docetaxel (Taxotere) treatment.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

MISSED DOSE

It is important that you receive docetaxel as scheduled by your doctor. If you miss a dose, contact your doctor immediately to obtain a new dosing schedule.

STORAGE

Store at room temperature or refrigerate between 36-77 degrees F (2-25 degrees C) and away from bright light. Once prepared, docetaxel should be given to you within 4 hours. Keep all medicines away from children and pets.

WARNING

Docetaxel has caused severe allergic reactions and swelling (fluid retention/edema) even with the use of preventative medications. This drug must not be used in patients who previously had an allergic reaction to it or other medications containing polysorbate 80. There is an increase risk of serious reactions (possibly fatal) in patients using docetaxel who have liver problems, who are getting higher doses, and in patients with non small cell lung cancer who have received certain other chemotherapy drugs known as

"platinums". If you have a low white blood cell count or liver problems, notify your doctor before using docetaxel. Seek immediate medical attention if you experience swelling, dizziness or fainting, difficulty breathing, irregular heart beat, severe swelling of the abdomen, skin rash, easy bleeding or bruising, sores in the mouth or throat, or symptoms of infection, such as fever and sore throat. Your doctor will closely monitor you and your blood counts and liver tests while you are receiving docetaxel.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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