**Docetaxel**

**Generic name:** Docetaxel

**Brand name:** TEOTAXOL®

**Dosage form:** Concentrate for solution for infusion 20 and 80 mg vials

**Drug class:** Mitotic inhibitors

**Indications:**

Docetaxel is a cytostatic medicine. Docetaxel inhibits the growth of cancer cells, finally leading to their extirpation. It may stop cancer cells from dividing and growing.

* Docetaxel is used to treat breast cancer, lung cancer, prostate cancer, stomach cancer, and head/neck cancer.
* Breast Cancer
* Non-Small Cell Lung Cancer (NSCLC)
* Hormone Refractory Prostate Cancer (HRPC)
* Gastric Adenocarcinoma (GC)
* Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN)

Docetaxel may also be used for purposes not listed in this medication guide.

**Contraindications**

Docetaxel should not be prescribed for patients with the following conditions:

* In patients with a known hypersensitivity or allergy to Docetaxel or any of the other ingredients of TEOTAXOL®.
* Pregnancy or breastfeeding.
* In those patients who the number of white blood cells or blood platelets is too low.
* Serious uncontrolled infections.
* Hepatic failure
* Acute Heart disease

**Mechanism of action**

Docetaxel is believed to have a twofold mechanism of antineoplastic activity: (1) inhibition of microtubular depolymerization, and (2) attenuation of the effects of bcl-2 and bcl-xL gene expression. Taxane-induced microtubule stabilization arrests cells in the G(2)M phase of the cell cycle and induces bcl-2 phosphorylation, thereby promoting a cascade of events that ultimately leads to apoptotic cell death. In preclinical studies, docetaxel had a higher affinity for tubulin and was shown to be a more potent inducer of bcl-2 phosphorylation than paclitaxel.

**Warning and precautions**

* This medicine is prescribed for your current condition. So do not use it in similar cases or recommend it to others.
* Take this medicine according to the treatment plan prescribed by the doctor and with the strict observance of the hours and intervals mentioned.
* Discontinue the use of medication only with a doctor and avoid abstinence.
* Docetaxel should not be given to patients who are allergic to Docetaxel or any of the other ingredients of this product.
* Docetaxel can harm an unborn baby or cause birth defects if the mother or the father is using this medicine.
* If you are a woman, do not use Docetaxel if you are pregnant. You may need to have a negative pregnancy test before starting this treatment. Use effective birth control to prevent pregnancy while you are using this medicine and for at least 6 months after your last dose.
* If you are a man, use effective birth control if your sex partner is able to get pregnant. Keep using birth control for at least 3 months after your last dose.
* Tell your doctor right away if a pregnancy occurs while either the mother or the father is using Docetaxel.
* It may be harder for you to get a woman pregnant while you are using this medicine. You should still use birth control to prevent pregnancy because the medicine can harm an unborn baby.
* You may have a life-threatening allergic reaction or a severe skin reaction. Get emergency medical help if you have signs of an allergic reaction: hives, burning eyes, skin pain, red or purple skin rash with blistering and peeling; fever, sore throat, wheezing, chest tightness, trouble breathing; feeling like you might pass out; swelling of your face, lips, tongue, or throat.
* This medicine contains alcohol. It is recommended not to drive or use machines immediately after a course of treatment. As in all cases, you should not drive a car or use machines if you feel dizzy or light-headed.
* You may be at risk of infection, so wash your hands often and try to avoid contact with people who have colds, flu or infections
* TEOTAXOL® may have unsafe effects on the bone marrow. The bone marrow may not be able to make cells found in the blood as well as it used to for a few weeks. That is why it is necessary to do regular blood tests to continue your treatment. If your white blood cell count is too low, your doctor may stop the treatment so long as there is enough white blood cell count.
* You will be given steroid medication to help prevent fluid retention. Keep using the steroid for as long as your doctor has prescribed.
* Do not receive any kind of vaccination without your doctor’s approval while taking TEOTAXOL® and after the end of the treatment (at least for three months after completion of treatment).
* Avoid coming into contact with anyone who has recently received a live vaccine. If it is not possible, wear a mask and cover your nose and mouth.
* Talk with your doctor before using products that have aspirin, blood thinners, garlic, ginseng, ginkgo, ibuprofen, pain killers, or vitamin E and similar products. These medications may increase the risk of bleeding with TEOTAXOL® concomitant use.
* Avoid alcohol drinks.
* Avoid smoking and tobacco.
* Talk with your doctor if you often use grapefruit or its juice in your diet.
* You may bleed more easily. Be careful and avoid injury.
* Be careful using sharp objects such as razors or nail clippers and also during the brushing or dental flossing or toothpicks. Use a soft toothbrush and an electric razor.
* Avoid exercise in which there is a risk of injury or bruising.
* Consult with your doctor before you receive any dental care.
* During infusion do not touch your eyes, your nose and your mouth. Wash your hands with soap after infusion session.

## How is docetaxel given?

Docetaxel is given as an infusion into a vein. A healthcare provider will give you this injection.

Docetaxel can be harmful if it gets on your skin during an IV infusion. If this happens, wash right away with soap and water. Tell your caregivers if you feel any burning, pain, or swelling around the IV needle when docetaxel is injected.

You may need frequent medical tests to be sure this medicine is not causing harmful effects. Your cancer treatments may be delayed based on the results. Your vision may also need to be checked.

You will be given steroid medication to help prevent fluid retention. Keep using the steroid for as long as your doctor has prescribed.

**What should I avoid while receiving Docetaxel?**

* Avoid driving or hazardous activity until you know how Docetaxel will affect you. Your reactions could be impaired.
* Avoid being near people who are sick or have infections. Tell your doctor at once if you develop signs of infection.
* Avoid activities that may increase your risk of bleeding or injury. Use extra care to prevent bleeding while shaving or brushing your teeth.
* Do not receive any kind of vaccination without your doctor’s approval while taking TEOTAXOL® and after the end of the treatment.
* Docetaxel contains alcohol and may cause a drunken feeling when the medicine is injected into your vein. Avoid drinking alcohol on the day of your docetaxel injection.
* Avoid coming into contact with anyone who has recently received a live vaccine. If it is not possible, wear a mask and cover your nose and mouth.
* Avoid smoking and tobacco.
* Do not touch your eyes, nose and your mouth. Wash your hands with soap after infusion session.

**Docetaxel side effects**

Taking any medication may cause side effects. In some cases, patients do not experience any side effects or the side effects of the drug disappear after a short time of taking the drug. Talk to your doctor if you experience any side effects while taking this medicine.

You may have a life-threatening allergic reaction or a severe skin reaction. Get emergency medical help if you have signs of an allergic reaction: hives, burning eyes, skin pain, red or purple skin rash with blistering and peeling; fever, sore throat, wheezing, chest tightness, trouble breathing; feeling like you might pass out; swelling of your face, lips, tongue, or throat.

You may have swelling in your intestines, which could cause death quickly. Call your doctor right away if you have stomach pain or tenderness, diarrhea, or fever.

Some side effects may occur during the injection. Tell your caregiver if you feel light-headed, or if you have trouble breathing or fast or irregular heartbeats.

Also call your doctor at once if you have:

* Pain, burning, irritation, or skin changes where the injection was given.
* Sudden vision problems including blurred vision or loss of vision.
* Redness or swelling in your arms or legs.
* Skin rash, redness, blistering, peeling, bleeding, or small red or white bumps that contain pus.
* Numbness, burning, or tingling in your hands or feet.
* Muscle weakness in your arms, legs, feet, or hands.
* Swelling, rapid weight gain, shortness of breath.
* Signs of tumor cell breakdown--weakness, muscle cramps, nausea, vomiting, diarrhea, fast or slow heart rate, tingling around your mouth.
* A feeling of being drunk--confusion, stumbling, extreme drowsiness.
* Liver problems--upper stomach pain, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes)
* Low blood cell counts, fever, chills, tiredness, mouth sores, skin sores, easy bruising, unusual bleeding, pale skin, cold hands and feet, feeling light-headed.

**Drug Interactions**

Consult your doctor about all the medications you are taking. TEOTAXOL® may interact with other medications.

Keep a list with you of all the medicines you use (including any prescription or nonprescription medicine, herbal preparation and vitamins) and show this list your doctor**.**

TEOTAXOL® may interact with some vaccine and increase the adverse effects of the vaccine.

This medicine should not be used concomitantly with immunosuppressive drugs.

Other drugs may affect Docetaxel, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

**Docetaxel use while Pregnancy and Breastfeeding**

Pregnancy: Category D

Using Docetaxel during pregnancy is strongly discouraged and patients should take precautions to avoid pregnancy.

Patients must not breast-feed while they are treated with TEOTAXOL®

Do not restart breast-feeding, unless doctor has allowed.

**Storage conditions**

* Store the medicine at temperatures below 30° C and stored away from light and moisture.
* Keep the medicine in the box until it is consumed.
* Keep the medicine out of the reach of children.
* The solution prepared for injection should be taken immediately.