

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Docetaxel Injection USP

docetaxel sterile solution

Read this carefully before you start taking **Docetaxel Injection USP** and each time you receive an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Docetaxel Injection USP**.

Serious Warnings and Precautions

- **Docetaxel Injection USP should be given to you by a healthcare professional experienced in the use of anti-cancer medicines.**
- **There is a higher risk of developing serious side effects, which may be life-threatening, in patients with liver disease. Docetaxel Injection USP should not be used if you have liver disease.**
- **Docetaxel Injection USP should not be used if you have a low white blood cell (neutrophil) count.**
- **Fatal cases of enterocolitis (inflammation of the digestive tract) have been reported.**
- **Docetaxel Injection USP may cause severe life threatening allergic reactions which require immediate stopping of the drug.**
- **An increase in new (second) cancers has happened in people treated with Docetaxel Injection USP alone, or together with certain other anti-cancer treatments. This includes blood cancers, such as acute myeloid leukemia.**

What is Docetaxel Injection USP used for?

Docetaxel Injection USP is used in adults for the treatment of:

- operable node-positive breast cancer in combination with doxorubicin and cyclophosphamide after you have had surgery
- advanced or metastatic (cancer that has spread to other parts of the body) breast cancer
 - alone; or
 - in combination with doxorubicin; or
 - in combination with capecitabine after previous anti-cancer treatment has failed

- advanced or metastatic non-small cell lung cancer:
 - alone; or
 - in combination with platinum agents
- metastatic ovarian cancer after other anti-cancer treatment has failed
- metastatic prostate cancer in combination with prednisone or prednisolone
- recurrent (cancer that has come back) or metastatic squamous cell carcinoma of the head and neck after other anti-cancer treatment has failed

How does Docetaxel Injection USP work?

Every cell in your body contains a supporting structure (almost like a “skeleton”). If this “skeleton” is changed or damaged, the cell can’t grow or reproduce.

Docetaxel Injection USP makes the “skeleton” in cancer cells unnaturally stiff. The cancer cells then can no longer grow or reproduce.

What are the ingredients in Docetaxel Injection USP?

Medicinal ingredients: docetaxel (anhydrous)

Non-medicinal ingredients: citric acid (anhydrous), ethanol anhydrous, polyethylene glycol 300, polysorbate 80

Docetaxel Injection USP comes in the following dosage forms:

Sterile solution: 10 mg / mL

Do not use Docetaxel Injection USP if:

- you have had an allergic reaction to docetaxel, other medicines containing polysorbate 80 or polyethylene glycol 300, or any of the other ingredients in the product
- you have a low white blood cell count (neutropenia)
- you have severe liver disease
- you are pregnant
- you are breastfeeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Docetaxel Injection USP. Talk about any health conditions or problems you may have, including if you:

- are pregnant or planning to get pregnant
- have not taken your premedication as directed by your healthcare professional
- suffer from alcoholism. Docetaxel Injection USP contains alcohol.
- have liver disease or epilepsy

- have been previously treated with an anti-cancer medicine called paclitaxel and have had an allergic reaction to it
- are already receiving treatments for cancer. Different types of cancer may develop from using Docetaxel Injection USP with certain other anti-cancer treatments.
- have kidney problems or high levels of uric acid in your blood
- are taking other medicines containing alcohol or propylene glycol. Too much alcohol can lead to side effects.

Other warnings you should know about:

Pregnancy and Breastfeeding – female patients:

- You must not receive Docetaxel for Injection USP if you are pregnant or think you might be pregnant. It may harm your unborn baby.
- If you are able to get pregnant:
 - Avoid becoming pregnant while you are being treated with Docetaxel Injection USP. Use effective birth control during treatment and for at least 2 months after the last dose.
 - Tell your healthcare professional right away if you become pregnant, or think you might be pregnant, during your treatment.
- It is not known if Docetaxel Injection USP passes into breastmilk. You must not breastfeed during your treatment and for 1 week after your last dose.

Pregnancy and fertility – male patients:

- Avoid fathering a child while you are being treated with Docetaxel Injection USP.
- During your treatment, use effective birth control each time you have sex with a woman who is pregnant, may be pregnant, or can get pregnant. Continue to use this birth control until 4 months after your last dose.
- Treatment with Docetaxel Injection USP can affect your ability to father a child. Talk to your healthcare professional about fertility preservation before starting treatment.

Patients being treated with Docetaxel Injection USP may experience:

- **Fluid retention:** This may begin as swelling in your legs. Your healthcare professional will prescribe medication to reduce the risk of having severe fluid retention. If the fluid retention is severe your healthcare professional may stop your treatment.
- **Heart problems:** You may feel an irregular and/or rapid heartbeat, severe shortness of breath, dizziness, and/or fainting. If this happens, talk to your healthcare professional immediately. Some of these symptoms can be serious and have been fatal in some patients.
- **Low white blood cell count:**
 - Your healthcare professional will need to check your blood at regular visits while you are being treated with Docetaxel Injection USP. Be sure to go to all your appointments. Your healthcare professional may decide to reduce your dose if your white blood cell count is low.

- Your white blood cells protect your body against infection. If your white blood cell count is low you are at risk for developing infections. Fever is the most common sign of infection. If you develop a fever or any other signs of infection, talk to your healthcare professional immediately.
- **Allergic reactions:** Allergic reactions may occur within a few minutes of starting Docetaxel Injection USP treatment. Serious allergic reactions with severe rash, difficulty in breathing and a drop in blood pressure may occur. Your healthcare professional will prescribe medication to reduce the risk of having an allergic reaction.
- **Vision problems:** If you experience vision problems, in particular blurred vision, you should immediately have your eyes and vision examined. This could be caused by a condition called cystoid macular edema where there is swelling of the retina. If this happens your healthcare professional may decide to stop your treatment.
- **Nerve pain:** Some people feel this pain as numbness, tingling, or burning in their hands and feet. This nerve pain is rarely severe and usually goes away after treatment is completed. Medication can be prescribed to make the pain more manageable. If the pain is severe, your healthcare professional may decide to reduce your dose or stop your treatment.
- **Rash:** This usually occurs on the feet and hands, but may also appear on the arms, face or body. The rash generally appears within a week after each Docetaxel Injection USP treatment, and disappears again before the next treatment. The rash is rarely serious, and it is rare for a patient to discontinue Docetaxel Injection USP therapy because of this rash. In some cases, your healthcare professional may decide to reduce your dose.
- **Second cancers:** An increase in new (second) cancers, including acute myeloid leukemia, myelodysplastic syndrome, non-Hodgkin lymphoma (types of blood cancer) and kidney cancer, may occur in patients who are treated with Docetaxel Injection USP alone or together with certain other anti-cancer treatments. These cancers may occur years after treatment with Docetaxel Injection USP.
- **Tumor lysis syndrome (TLS):** This is the sudden, rapid death of cancer cells due to treatment. TLS can cause life-threatening kidney failure and heart problems.
- **Severe skin reactions:** Symptoms may include blistering, peeling or bleeding on any part of your skin with or without a rash, and you may also have flu-like symptoms such as fever, chills, or muscle aches. If you develop severe skin reactions, talk to your healthcare professional immediately.
- **Weakness:** Many patients receiving Docetaxel Injection USP experience a feeling of weakness during their treatment. If weakness is accompanied by joint or muscle pain, make sure to tell your healthcare professional as they can prescribe pain medication to help make you feel more comfortable.
- **Hair loss:** Loss of the hair (including eyebrows, eyelashes, pubic hair, underarm hair and the hair on your head), occurs in most patients taking Docetaxel Injection USP. Hair loss may happen shortly after treatment has begun. Your hair should grow back once you've finished the treatment. However, some patients may experience permanent hair loss. In the meantime, your healthcare professional can refer you to a special store that carries turbans and wigs specifically for patients with cancer.

- **Driving and using machines:** You may feel the effects of the alcohol contained in Docetaxel Injection USP, which can cause you to feel drunk or intoxicated. This may impair your ability to drive or use machinery. Do not perform tasks that require special attention until these effects have passed.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines, or drugs that you bought without a prescription.

The following may interact with Docetaxel Injection USP:

- cyclosporine, used to suppress the immune system
- antibiotics, used to treat bacterial infections, such as rifampin, troleandomycin, erythromycin, clarithromycin, telithromycin
- terfenadine, an antihistamine used to treat allergies
- antifungal medicines, used to treat fungal infections, such as ketoconazole, itraconazole, voriconazole
- medicines called protease inhibitors, used to treat HIV infection, such as ritonavir, indinavir, nelfinavir, saquinavir
- nefazodone, used to treat depression
- pain relievers
- sleep aids, such as diazepam or other medicines called “benzodiazepines”

How to take Docetaxel Injection USP:

- Docetaxel Injection USP will be given to you by a healthcare professional in a hospital or clinic setting.
- It will be given to you intravenously, by an injection directly into your vein (IV).

How often will I get treated with Docetaxel Injection USP?

- Docetaxel Injection USP is usually given in a 1-hour dose every 21 days. Every patient is different; your healthcare professional will determine what dose of Docetaxel Injection USP is right for you and how often you should receive it.
- Your healthcare professional may prescribe Docetaxel Injection USP either alone, or in combination with other anti-cancer medicines, such as doxorubicin, cyclophosphamide, platinum agents (cisplatin, carboplatin), capecitabine, prednisone or prednisolone.

What do I need to do before each Docetaxel Injection USP treatment?

- Every time you receive Docetaxel Injection USP, you will be asked to take some premedication. The purpose of this premedication is to reduce the fluid retention you may experience during treatment. Usually, the premedication consists of corticosteroid pills that are taken orally one day before each Docetaxel Injection USP treatment, on the same day of each treatment, and one day after each treatment. Your healthcare professional will tell you exactly what premedication you need to take and for how long.

- Your healthcare professional may also decide to give you other medications to reduce the risk of infection and allergic reaction.
- If you forget to take your premedication as directed, make sure to tell your healthcare professional before you get your Docetaxel Injection USP treatment.

Usual dose:

Your healthcare professional will decide on the dose that is right for you depending on your weight and your general condition.

Overdose:

If you think you, or a person you are caring for, have been given too much Docetaxel Injection USP contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

This medicine needs to be given on a fixed schedule. If you miss an appointment, talk to your healthcare professional immediately.

What are possible side effects from using Docetaxel Injection USP?

These are not all the possible side effects you may have when taking Docetaxel Injection USP. If you experience any side effects not listed here, tell your healthcare professional.

Like many anti-cancer medicines, Docetaxel Injection USP may have side effects. Most of the side effects that occur with Docetaxel Injection USP are manageable. Occasionally, it is necessary to stop the treatment. If you **do** experience side effects, your healthcare professional can give you a number of medications and explain techniques to help make you feel more comfortable.

- nausea, diarrhea, vomiting
- loss of appetite
- change in taste
- constipation, stomach pain
- fatigue
- sores in the mouth
- nail changes
- fever
- hair loss
- rash

When Docetaxel Injection USP is used in combination with capecitabine, the frequency of side effects may differ. In particular, the risk of developing a rash of the hands and feet is increased. Talk to your healthcare professional for more information.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Muscle pain, joint pain		√	
Nerve pain: numbness, tingling, or burning in the hands and feet		√	
Weakness	√		
UNCOMMON			
Allergic reactions: difficulty swallowing or breathing, tightness in the throat or chest, rash, hives, swelling of the face, lips, tongue or throat, drop in blood pressure, nausea, vomiting, flushing, fever or chills		√	
Low white blood cell count: fever or signs of infection like redness or swelling at the injection site, a cough that brings up mucus, sore throat, chills, generally feeling unwell		√	
Heart problems: chest pain, rapid or irregular heartbeat, dizziness, nausea, shortness of breath, fainting, loss of consciousness		√	
Liver problems: loss of appetite, abdominal pain, dark urine, light-coloured stools, yellowing of the skin or eyes		√	
Kidney problems: nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, mental status changes (drowsiness, confusion, coma)			
Enterocolitis (inflammation of the digestive tract): persistent vomiting or diarrhea, abdominal pain		√	
Vision problems: blurred vision, changes in vision		√	
New (second) cancers: including the blood cancers acute myeloid leukemia, myelodysplastic syndrome, non-Hodgkin lymphoma and kidney cancer		√	
UNKNOWN FREQUENCY			
Electrolyte imbalance: weakness, confusion, muscle pain or cramps, irregular heartbeat		√	
Injection site reaction: redness, swelling, itching at the site of a previous infusion		√	
Severe skin reactions: blistering, peeling or bleeding of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, red, scaly rash with bumps under the skin, may be accompanied by flu-like symptoms (fever, chills, headache, cough, body aches, swollen glands)		√	
Tumor Lysis Syndrome (sudden, rapid death of cancer cells due		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
to treatment): nausea, vomiting, confusion, delirium, seizures (fits), pain in your side, reduced amount of urine or darkening of urine			
Muscle inflammation		√	
Fluid retention: swollen or puffy legs or hands, feeling heavy, achy or stiff, rapid weight gain, shortness of breath		√	
Lung and breathing problems: severe difficulty breathing, including shortness of breath at rest or with activity, rapid breathing, wheezing or cough, chest pain, fatigue, fever and chills		√	
Bone marrow suppression (a large decrease in the production of blood cells and platelets by the bone marrow): bleeding, bruising, chills, fatigue, fever, weakness, shortness of breath or other signs of infection		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Your healthcare professional will store Docetaxel Injection USP. The unopened vials should be stored between 2°C and 25°C in their original packaging. Protect from light and freezing.

Keep out of reach and sight of children.

If you want more information about Docetaxel Injection USP:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <https://www.pfizer.ca/>, or by calling 1-800-463-6001.

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