PART III: CONSUMER INFORMATION

[Pr]Docetaxel Injection USP

10 mg/mL

Sterile Solution

For Intravenous Infusion
Must be diluted directly in infusion solution

This leaflet is part III of a three-part "Product Monograph" published when the drug is approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Docetaxel Injection USP. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Docetaxel Injection USP is used as or for the:

- adjuvant treatment of patients with operable node-positive breast cancer in combination with doxorubicin and cyclophosphamide
- advanced or metastatic breast cancer, as single agent or in combination with doxorubicin; or in combination with capecitabine (Xeloda®) after failure of previous anti-cancer drugs
- advanced or metastatic non-small cell lung cancer, as single agent or in combination with platinum derivatives
- metastatic ovarian cancer after failure of previous anti-cancer drugs
- metastatic prostate cancer in combination with prednisone or prednisolone
- recurrent or metastatic squamous cell carcinoma of the head and neck after failure of previous anti-cancer drugs

What it does:
Here's how Docetaxel Injection USP works: 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 cells unnaturally stiff. The cancer cells then can no longer grow or reproduce.

When it should not be used:
Docetaxel Injection USP should not be used if:

- you have had an allergic reaction to docetaxel or to polysorbate 80 or any of the other ingredients in the product;
- you have a low white blood cell count (neutropenia);
- you have a severe liver disease;
- you are pregnant or breast feeding.

What the medicinal ingredient is:
The active ingredient in Docetaxel Injection USP is Docetaxel (anhydrous).

What the nonmedicinal ingredients are:
The non-active ingredients in Docetaxel Injection USP are polysorbate 80, ethanol anhydrous, citric acid (anhydrous) and polyethylene glycol 300.

What dosage forms it comes in:
Docetaxel Injection USP is available as a 10 mg/mL solution packaged in single-use vials of 2 mL and in multidose vials of 8 mL and 16 mL. It must be diluted directly in 0.9% Sodium chloride solution or 5 % dextrose solution prior to administration. The vial is wrapped in a protective plastic sleeve. It is called ONCO-TAIN® The wrap will reduce the risk of a spill if the vial breaks. The vial stoppers are latex-free.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Docetaxel Injection USP should be given under the supervision of a doctor experienced in the use of anti-cancer drugs.

There is a higher risk of developing severe adverse reactions, 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 white blood cell (neutrophil) count of less than 1,500 cells/mm^3.

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 discontinuation of the drug.

A possible serious side effect that may occur is acute

myeloid leukemia. No studies have been conducted to assess the carcinogenic potential of Docetaxel Injection USP.

BEFORE your Docetaxel Injection USP injection, talk to your doctor if:

- you are pregnant or planning to get pregnant
- you have not taken your premedication as directed
- you suffer from alcoholism, liver disease or epilepsy.
- you have been previously treated with a medicine called paclitaxel and have had an allergic reaction to it.

Patients receiving Docetaxel Injection USP may experience:
- Fluid retention. Your doctor will prescribe you medication to reduce the risk of having severe fluid retention.

- Low blood cell count: Your doctor will need to check your blood at regular visits while you are using this medicine. Be sure to go to all your appointments. Your doctor may decide to reduce your dose if your white blood cell count is low.

- Allergic reactions: Allergic reactions may occur within a few minutes following the initiation of Docetaxel Injection USP treatment. Severe allergic reactions with severe rash, difficulty in breathing (bronchospasm), low blood pressure (hypotension) may occur. Your doctor will prescribe you medication to reduce the risk of having an allergic reaction.

- Nerve pain (peripheral neurotoxicity): 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. In some cases, your doctor 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 is rarely serious, and it is rare for a patient to discontinue Docetaxel Injection USP therapy because of rash or other skin problems. In some cases, your doctor may decide to reduce your dose.

-Feeling drunk or intoxicated: you may feel the effects of the alcohol contained in Docetaxel Injection USP. This may impair your ability to drive or use machinery.

INTERACTION WITH THIS MEDICATION

Drugs that may interact with Docetaxel Injection USP include, but are not limited to:

- cyclosporine
- terfenadine
- ketoconazole
- erythromycin
- protease inhibitors (e.g. ritonavir, indinavir, nelfinavir, saquinavir)
- itraconazole
- clarithromycin
- nafazodone
- telithromycin
- voriconazole
- pain relievers
- sleep aids, such as diazepam or other medicines called “benzodiazepines”.

Tell your doctor if you are taking any medicine which has been prescribed for you or which you bought without a prescription.

PROPER USE OF THIS MEDICATION

How often will I get treated with Docetaxel Injection USP?

Docetaxel Injection USP is usually given in a 1-hour intravenous (IV) dose every 21 days. Every patient is different; your doctor will determine what dose of Docetaxel Injection USP is right for you and how often you should receive it.

Your doctor may prescribe Docetaxel Injection USP either alone, or in combination with other anti-cancer drugs, such as doxorubicin, cyclophosphamide, platinum derivatives (cisplatin, carboplatin), capecitabine (Xeloda®), prednisone or prednisolone.

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

The administration of Docetaxel Injection USP requires you to take medication before each treatment begins. 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 doctor or nurse will tell you exactly what premedication you need to take and for how long.

Your doctor may also decide to give you other medications to reduce the risk of infection.

If you forget to take your premedication as directed, make sure to tell your doctor or nurse before you get your Docetaxel Injection USP treatment.

Do not use product if solution shows haziness, particulate matter, discolouration or leakage.

Overdose:

In case of drug overdose, contact a health care practitioner, 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, call your doctor for instructions.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like many anti-cancer drugs, 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 doctor can give you a number of medications and explain techniques to help make you feel more comfortable.

The most common side effects are:
- Nausea, diarrhea, vomiting
- Fatigue
- Stomatitis: sores in the mouth
- Nail changes
- Low white blood cell count (neutropenia)
- Fever
- Hair Loss
- Weakness
- Rash
- Nerve pain
- Fluid retention
- Swelling at the injection site

Low White Blood Cell Count: Your white blood cells protect your body against infection. There are three types of white blood cells; the most important in preventing infections are cells called neutrophils. Many anti-cancer drugs, including Docetaxel Injection USP, cause a temporary drop in neutrophils (a condition known as neutropenia); however, most people receiving Docetaxel Injection USP do not develop infections, even when they have neutropenia. Your doctor will be checking routinely your white blood count, and will alert you if your white count is low.

Fever is one of the most common signs of infection. So if you have a fever, make sure to tell your doctor or nurse immediately.

Hair Loss: Loss of the hair (including eyebrows, eyelashes, pubic hair, underarm hair and the hair on your head), which is known as alopecia, 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 doctor or nurse can probably refer you to a special store that carries turbans and wigs specifically for patients with cancer.

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 doctor or nurse; your doctor can prescribe pain medication to help make you feel more comfortable.

Rash: Patients on Docetaxel Injection USP may develop a 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 rash or other skin problems.

Nerve Pain: Patients receiving Docetaxel Injection USP may experience 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. However, if you are bothered by nerve pain, make sure to tell your doctor or nurse; your doctor can prescribe pain medication to help make you feel more comfortable.

Fluid Retention: Fluid retention can occur in patients receiving Docetaxel Injection USP. It may begin as swelling on the legs. Your doctor will prescribe medication, which is important for you to take to reduce the likelihood that the fluid retention will be serious or cause your treatment to be discontinued.

Blurred vision: In case of vision problems, you should have a complete eye and vision examination. If cystoid macular edema (blurred vision due to swelling of the retina within the eye) is diagnosed, your doctor may stop your treatment.

When Docetaxel Injection USP is used in combination with capecitabine (Xeloda®), the frequency of side effects may differ. In particular, the risk of developing a rash of the hands and feet is increased. You should refer to your doctor for more details.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Muscle pain		√	
	Nerve pain such as numbness, tingling, or burning in the hands and feet		√	
	Weakness	√		
Uncommon	Allergic reactions such as trouble breathing, tightness in the throat, rash, hives, swelling of the lips or tongue or low blood pressure		√	
	Fever or signs of infection, like redness or swelling at the injection site, a cough that brings up mucus, or a sore throat		√	
	Cardiac problems with symptoms such as: chest pain, rapid or irregular heart beat dizziness, nausea, shortness of breath, loss of consciousness		√	
	Liver problems such as loss of appetite, dark urine, light-coloured stools, yellowing of the skin or eyes		√	
	Kidney problems		√	
	Persistent vomiting or diarrhea; abdominal pain		√	
	Visual disturbances		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown frequency	Electrolyte imbalance: weakness, confusion, muscle pain or cramps, irregular heartbeat		√	
	Redness, swelling, itching at the site of a previous infusion following later treatment.		√	

This is not a complete list of side effects. If you have any unexpected effects while taking Docetaxel Injection USP, contact your doctor or pharmacist.

HOW TO STORE IT

The unopened vials should be stored between 2°C and 25°C in their original packaging. Protect from light and freezing.

Reporting Suspected 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.

MORE INFORMATION

Your doctor, pharmacist and nurse are always your best source of information about your condition and your

treatment. If you have additional questions or concerns, be sure to ask them.

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting the sponsor, Pfizer Canada Inc. at **1-800-463-6001**.

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