

PART III: CONSUMER INFORMATION

Pr **ABRAXANE®** for Injectable Suspension paclitaxel powder for injectable suspension nanoparticle, albumin-bound (nab®) paclitaxel

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

ABOUT THIS MEDICATION

What the medication is used for:

ABRAXANE is a prescription cancer medicine. It is injected into a vein and it is used to treat advanced breast cancer and metastatic pancreatic cancer.

WHAT IS CANCER?

Under normal conditions, the cells in your body divide and grow in an orderly, controlled way. Cell division and growth are necessary for the human body to perform its functions and to repair itself, when necessary. Cancer cells are different from normal cells because they are not able to control their own growth. The reasons for this abnormal growth are not yet fully understood. A tumor is a mass of unhealthy cells that are dividing and growing fast and in an uncontrolled way. When a tumor invades surrounding healthy body tissue, it is known as a malignant tumor. A malignant tumor can spread (metastasize) from its original site to other parts of the body if not found and treated early.

What it does:

ABRAXANE is a type of medical treatment called chemotherapy. The purpose of chemotherapy is to kill cancer cells or prevent their growth.

All cells, whether they are healthy cells or cancer cells, go through several stages of growth. During one of the stages, the cell starts to divide. ABRAXANE may stop the cells from dividing and growing, so they eventually die. In addition, normal cells may also be affected by ABRAXANE causing some of the side effects. (See SIDE EFFECTS AND WHAT TO DO ABOUT THEM below.)

When it should not be used:

ABRAXANE should not be given to patients with dangerously low white blood cell counts or to patients who are allergic to the drug or any of the components of it.

What the medicinal ingredient is:

Paclitaxel

What the important nonmedicinal ingredients are:

Human albumin

What dosage form it comes in:

ABRAXANE is supplied in vials of 100 mg paclitaxel each of which contains the product in a powder form. It can be used after the health professional adds a solution to it. At that point, ABRAXANE is injected into a vein [intravenous (i.v.) infusion] over 30 minutes.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- ABRAXANE should be administered under the supervision of a doctor who works with cancer medicines.
- ABRAXANE should not be given to patients with dangerously low white blood cell counts. To make sure that your blood counts are in the proper range, you will be asked to have frequent tests.
- Your doctor has prescribed this particular paclitaxel product which contains no solvents, unlike other paclitaxel products. This may reduce some of the adverse effects that may be caused by these other ingredients, such as allergic reactions. Your doctor may not wish any other paclitaxel products to be substituted for Abraxane, so you may wish to check to ensure you have received the correct medication.

BEFORE you use ABRAXANE, talk to your doctor or pharmacist if:

- you are experiencing numbness or tingling in your extremities;
- you suspect that you are pregnant, plan to become pregnant or are nursing. ABRAXANE can cause harm to the fetus. Avoid becoming pregnant while taking ABRAXANE and if you become pregnant during treatment, contact your doctor immediately. Men should be advised to use effective contraception and to avoid fathering a child while receiving treatment with ABRAXANE and up to six months after treatment;
- you are breast-feeding or plan to breast-feed. Breast-feeding must be discontinued while taking ABRAXANE;
- you have any allergies to this drug or its ingredients or components of the container.
- you have a history of interstitial lung disease, multiple allergies, chronic cough or shortness of breath.
- you have or have had heart problems, fainting spells (syncope), or an irregular heartbeat.
- you have liver or kidney problems

INTERACTIONS WITH THIS MEDICATION

No studies have been done on how this drug interacts with other drugs.

PROPER USE OF THIS MEDICATION

Usual Adult Dose:

For the treatment of advanced breast cancer ABRAXANE is injected into a vein [intravenous (i.v.) infusion] over 30 minutes at a dose of 260 mg/m² every 3 weeks. The usual dose for metastatic pancreatic cancer is 125 mg/m² over 30-40 minutes on days 1, 8, and 15 of each 28-day treatment cycle with gemcitabine given immediately after ABRAXANE.

Overdose:

There is no known antidote for ABRAXANE overdosage.

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Talk to your doctor if you have missed a treatment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Most patients taking ABRAXANE[®] will experience side effects, although it is not always possible to tell whether such effects are caused by ABRAXANE, another medicine they may be taking, or the cancer itself. Important side effects are described below; however, some patients may experience other side effects that are less common. Report any unusual symptoms to your doctor.

Important side effects observed in studies of patients taking ABRAXANE were as follows:

Hair Loss: Complete hair loss, or alopecia, almost always occurs with ABRAXANE. This usually involves the loss of eyebrows, eyelashes, and pubic hair, as well as scalp hair. It can occur suddenly after treatment has begun, but usually happens 14 to 21 days after treatment. Hair generally grows back after you've finished your ABRAXANE treatment.

Infections Due to Low White Blood Cell Count: Among the body's defenses against bacterial infections are white blood cells. Between your ABRAXANE treatment cycles, you will often have blood tests to check your white blood cell counts. ABRAXANE usually causes a brief drop in white blood cells. If you have a fever (temperature above 100.4°F/38°C) or other sign of infection, tell your doctor right away. Sometimes serious infections develop that require treatment in the hospital with antibiotics. Serious illness or death could result if such infections are not treated when white blood cell counts are low.

Numbness, Tingling, or Burning (Neuropathy): These symptoms in the hands and/or feet occur often with ABRAXANE and usually get better or go away without medication within three weeks of interrupting treatment. Weakness or paralysis of the muscles of the face have also been reported with the use of ABRAXANE. Be sure to tell your doctor about any numbness, tingling or burning that you have in your face, hands or feet so that he/she can decide the best approach for relief of your symptoms. Sometimes it is necessary to interrupt treatment with ABRAXANE

until these symptoms improve. After improvement, treatment can be restarted at a lower dose.

Fatigue and Weakness: ABRAXANE may cause fatigue, weakness, lethargy and malaise. These side effects are usually self-limited and do not require dose modification or interruption.

Low Red Blood Cell Count: Red blood cells deliver oxygen to tissues throughout all parts of the body and take carbon dioxide from the tissues by using a protein called hemoglobin. A lowering of the volume of red blood cells may occur following ABRAXANE treatment causing anemia. Some patients may need a blood transfusion to treat the anemia. Patients can feel tired, tire easily, appear pale, and become short of breath. Contact your doctor if you experience any of these symptoms following ABRAXANE treatment.

Mouth or Lip Sores (Mucositis): Some patients develop redness and/or sores in the mouth or on the lips. These symptoms might occur a few days after the ABRAXANE treatment and usually decrease or disappear within one week. Talk with your doctor about proper mouth care and other ways to prevent or reduce your chances of developing mucositis.

Joint and Muscle Pain: You may get joint and muscle pain a few days after your ABRAXANE treatment. These symptoms usually disappear in a few days. Although pain medicine may not be necessary, tell your doctor if you are uncomfortable.

Stomach Upset and Diarrhea: Some patients experience nausea, vomiting, and/or diarrhea following ABRAXANE use. If you experience nausea or stomach upset, tell your doctor because medicines can be given that almost always reduce or eliminate these symptoms. Diarrhea will usually disappear without treatment; however, if you experience severe abdominal or stomach area pain and/or severe diarrhea, tell your doctor right away.

Heart and Blood Vessel (Cardiovascular) Effects:

ABRAXANE may cause a drop in heart rate (bradycardia), low blood pressure (hypotension), irregular heartbeat, and chest pain. The patient usually does not notice these changes. You should notify your doctor if you feel dizziness, chest pain, shortness of breath, or faint during treatment with ABRAXANE.

Irritation at the Injection Site: ABRAXANE may cause irritation at the site where it enters the vein. Reactions may include discomfort, redness, swelling, inflammation (of the surrounding skin or of the vein itself), and ulceration (open sores). These reactions are usually caused by the i.v. (intravenous) fluid leaking into the surrounding area. *If you notice anything unusual at the site of the injection (needle), either during or after treatment, tell your doctor right away.*

Respiratory: ABRAXANE may cause shortness of breath and cough. Sometimes these symptoms are a sign of serious lung inflammation due to ABRAXANE. You should notify your doctor right away if you develop a cough and/or shortness of breath while taking ABRAXANE treatment.

Ability to Drive and Use Machines: Adverse events such as fatigue, weakness and malaise may affect your ability to drive and use machines.

Other Side Effects: ABRAXANE may cause mild allergic reactions during the infusion such as flushing. ABRAXANE may also cause vision disturbances, changes in your nails and rash. Tell your doctor if you experience blurry or decreased central vision. Rare occurrences of severe allergic reactions have been reported with ABRAXANE. In very rare cases these reactions have been fatal. Patients who experience a severe allergic reaction to ABRAXANE should not receive ABRAXANE again.

Talk with your doctor or other healthcare professional to discuss ways to prevent or reduce some of these side effects. Because this leaflet does not include all possible side effects that can occur with ABRAXANE, it is important to talk with your doctor about other possible side effects.

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	fever		X	
	numbness, tingling or burning in the extremities		X	
Uncommon	redness, swelling, irritation or discomfort at the injection site		X	
	cough, shortness of breath		X	
Rare	fainting, dizziness, shortness of breath, chest pain		X	

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Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very Rare	Symptoms of tumor lysis syndrome: lack of urination, severe muscle weakness, heart rhythm disturbances, and seizures			X

This is not a complete list of side effects. For any unexpected effects while taking ABRAXANE, contact your doctor or pharmacist.

HOW TO STORE IT

Your doctor or pharmacist will store ABRAXANE for you.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:
<http://www.celgenecanada.net> or by contacting:
Celgene Inc. at: 1-877-923-5436 extension 4850.

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

This leaflet was prepared by Celgene Inc.

Last revised: August 31, 2018