

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ABRAXANE**[®] for Injectable Suspension

Paclitaxel powder for injectable suspension

nanoparticle, albumin-bound (nab[®]) paclitaxel

Read this carefully before you start taking ABRAXANE. 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 ABRAXANE.

Serious Warnings and Precautions

- ABRAXANE should only be prescribed by a healthcare professional who has experience with anti-cancer medicines. ABRAXANE should not be substituted with or for other paclitaxel products.
- ABRAXANE can cause the following side effects when taken with a medicine called gemcitabine:
 - **Sepsis** (blood infection). The risk is higher if you have pancreatic cancer and bile system problems.
 - **Pneumonitis** (infection of lung tissue) which in some cases can cause death. Your healthcare professional will monitor your lung health during treatment.
 - **Blood problems**, like bone marrow suppression (low white and/or red blood cell or platelet count). You should not be given ABRAXANE if you have very low white blood cell levels. Your healthcare professional will monitor your white blood cell levels.

See the 'Serious side effects and what to do about them' table, below, for more information on these and other serious side effects.

- Patients 65 years and older: There are higher risk of side effects such as nose bleeds, diarrhea, dehydration, tiredness and swelling. For patients 75 years and older, there are higher risks of side effects like loss of appetite, dehydration, blood and nervous system problems. Your healthcare professional will decide if ABRAXANE is right for you.

What is ABRAXANE used for?

ABRAXANE is used to treat the following cancers that have spread to other parts of the body:

- breast cancer, and
- pancreatic cancer, when treated in combination with a medicine called gemcitabine.

How does ABRAXANE work?

ABRAXANE is a type of anti-cancer treatment called chemotherapy. ABRAXANE may stop the cancer 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 "What are possible side effects from using ABRAXANE?" below.)

What are the ingredients in ABRAXANE?

Medicinal ingredient: Paclitaxel

Non-medicinal ingredient: Human albumin

ABRAXANE comes in the following dosage forms:

Lyophilized powder for suspension: 100 mg

Do not use ABRAXANE if:

- you have very low white blood cell counts
- you are allergic to paclitaxel or any of the other ingredients in this medicine or the container

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

- are experiencing numbness or tingling in your extremities;
- have a history of interstitial lung disease, multiple allergies, chronic cough or shortness of breath;
- have or have had heart problems, fainting spells (syncope), or an irregular heartbeat;
- have liver or kidney problems.

Other warnings you should know about:

Heart problems: ABRAXANE can cause heart rhythm problems. Your healthcare professional will monitor your heart rhythm using an electrocardiogram (ECG).

Hypersensitivity (allergic) reactions: ABRAXANE can cause severe allergic reactions, including anaphylactic reactions, which can cause death.

Nervous system problems: ABRAXANE can cause numbness, tingling or burning feeling in your face, hands or feet. Tell your healthcare professional if you have these symptoms.

Eye problems: ABRAXANE may cause eye problems. Tell your healthcare professional if you have blurry vision or have trouble seeing. They will check your eye health.

See the 'Serious side effects and what to do about them' table, below, for more information on these and other serious side effects.

Pregnancy, breast-feeding and fertility:

Female patients:

- ABRAXANE can harm your unborn baby.
- Avoid getting pregnant while you are taking ABRAXANE. Women of childbearing age must use highly effective birth control during treatment with ABRAXANE and for at least 6 months after the last dose of ABRAXANE.
- If you are pregnant, able to get pregnant or are planning to have a baby, ask your healthcare professional for advice before taking ABRAXANE.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with ABRAXANE.
- Do not breast-feed while you are taking ABRAXANE.

- ABRAXANE may affect your ability to have a child.

Male patients:

- Avoid fathering a child during treatment with ABRAXANE and for up to 6 months after stopping treatment.
- Use effective birth control during treatment with ABRAXANE.
- ABRAXANE may affect your ability to father a child. Talk to your healthcare professional about options you may have to father a child.

Driving and using machines: ABRAXANE can cause tiredness, weakness and discomfort. Before you drive or do tasks that require special attention, wait until you know how you respond to ABRAXANE

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ABRAXANE:

- medicines for fungal infections such as ketoconazole
- medicines used to treat bacterial infections (antibiotics) such as erythromycin, rifampicin
- medicines used to treat depression such as fluoxetine, St. John's Wort
- medicines used to lower cholesterol such as gemfibrozil
- medicines used to prevent blood clots such as clopidogrel
- medicines used to treat heartburn such as cimetidine
- medicines for HIV infection such as ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine
- medicines used to prevent seizures such as carbamazepine, phenytoin
- grapefruit, Seville oranges, starfruit

How to take ABRAXANE:

- ABRAXANE will be given to you by a healthcare professional.
- The powder is first mixed into a solution. This solution is then given to you through a vein (intravenously).

Usual dose:

- The dose you will receive will depend on your disease and will be measured based on your body size.
 - For breast cancer: ABRAXANE is injected into a vein over 30 minutes every 3 weeks.
 - For pancreatic cancer: ABRAXANE is injected into a vein over 30-40 minutes on days 1, 8, and 15 of each 28-day treatment cycle. You will also receive treatment with another medicine, gemcitabine. Gemcitabine is given through your veins. Your healthcare professional will determine your dose and schedule.
- Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you experience serious side effects.

Overdose:

There is no known antidote for ABRAXANE overdosage.

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

Missed Dose:

- ABRAXANE needs to be given on a fixed schedule. Talk to your healthcare professional if you have missed a treatment.

What are possible side effects from using ABRAXANE?

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

- Hair loss
- Tiredness, weakness
- Mouth or lip sores
- Dry throat or nose
- Mouth fungus
- Joint, muscle or bone pain
- Constipation
- Dehydration
- Difficulty swallowing
- Nose bleeds
- Nail changes
- Rash, itchy skin
- Confusion
- Mood changes, depression, trouble sleeping
- Light headedness

ABRAXANE can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how ABRAXANE is affecting your blood, heart, liver, pancreas and kidneys.

| 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 | |
| VERY COMMON | | | |
| Blood disorders (low white and/or red blood cell or platelet count): feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills | | X | |
| Gastrointestinal problems: diarrhea, stomach pain, nausea, vomiting, bloating, bloody stool | X | | |
| COMMON | | | |

| | | | |
|--|--|---|--|
| Heart problems: fast heartbeat, palpitations, irregular heartbeat, chest pain, difficulty breathing, fainting, low blood pressure, swelling and pain in one part of the body, pain or tenderness or swelling in your arm or leg, skin that is red or warm, tingling or numbness, pale skin, muscle pain or spasms | | X | |
| Injection Site Reactions: blistering, itching, pain, redness, severe skin damage, tenderness, warmth in the area around the injection | | X | |
| Kidney problems: nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, mental status changes | | X | |
| Pneumonitis (inflammation of the lung tissue): shortness of breath, cough, fatigue, loss of appetite, unintentional weight loss | | X | |
| Sepsis (infection of the blood): fever or dizziness, chills, high or very low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat | | X | |
| Nervous system problems: numbness, tingling or burning on your face, hands, feet | | X | |
| UNCOMMON | | | |
| Stroke (bleeding or blood clot in the brain): sudden numbness, weakness or tingling of the face, arm, or leg, particularly on one side of the body, sudden headache, blurry vision, difficulty swallowing or speaking, or lethargy, dizziness, fainting, vomiting, trouble understanding, | | X | |

| | | | |
|---|--|---|---|
| trouble with walking and loss of balance | | | |
| RARE | | | |
| Hypersensitivity (allergic reaction): fainting, dizziness, shortness of breath, chest pain | | | X |
| VERY RARE | | | |
| Tumor lysis syndrome (the sudden, rapid death of cancer cells due to the treatment): lack of urination, severe muscle weakness, heart rhythm disturbances, and seizures | | | X |
| UNKNOWN | | | |
| Eye disorders: blurred vision, loss of vision in eye, increased sensitivity of the eyes to light, eye pain or redness, swelling and itching of the eyelids, decreased sharpness of vision, eye irritation, blocked eye veins | | X | |
| Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less urine | | X | |

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 ABRAXANE for you.
- Keep out of reach and sight of children.

If you want more information about ABRAXANE:

- 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.bms.com/ca/en>, or by contacting 1-866-463-6267.

This leaflet was prepared by Bristol-Myers Squibb Canada, Montreal, Canada H4S 0A4.

Last Revised: MAR 08, 2024