

ABRAXANE®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ABRAXANE?

ABRAXANE contains the active ingredient paclitaxel. ABRAXANE is used to treat breast cancer, lung cancer or pancreatic cancer.

For more information, see Section [1. Why am I using ABRAXANE?](#) in the full CMI.

2. What should I know before I use ABRAXANE?

Do not use if you have ever had an allergic reaction to paclitaxel or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant (for males, if your partner plans to become pregnant) or are breastfeeding.

For more information, see Section [2. What should I know before I use ABRAXANE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ABRAXANE and affect how it works. See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ABRAXANE?

- Your doctor will decide what dose of ABRAXANE you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.
- ABRAXANE is usually given as an infusion (drip) into a vein over 30 minutes.

More instructions can be found in Section [4. How do I use ABRAXANE?](#) in the full CMI.

5. What should I know while using ABRAXANE?

Things you should do	
	<ul style="list-style-type: none">• Call your doctor straight away if you become pregnant while you are being treated with this medicine• Tell any other doctors, dentists, and

pharmacists who are treating you that you are being given this medicine, especially if you are about to be started on any new medicine

- If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with this medicine. It may affect other medicines used during surgery.
- Keep all your doctor's appointments so your progress can be checked.
- You have an increased chance of getting an infection or bleeding. Precautions should be taken to reduce your risk of infection or bleeding; see Section [5. What should I know while using ABRAXANE?](#) in the full CMI.
- Your body breaks down ABRAXANE and uses it to fight cancer. The breakdown products

	<p>may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen. Precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period; see Section 5. What should I know while using ABRAXANE? in the full CMI.</p>
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Some people may feel tired or dizzy after being given Abraxane. If this happens to you, do not drive or use any tools or machines.

For more information, see Section [5. What should I know while using ABRAXANE?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, ABRAXANE can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious and you may require medical attention. For more information, including what

to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ABRAXANE[®] (ah-BRAKS-ane)

Active ingredient: paclitaxel (pak-li-tax-el)

Consumer Medicine Information (CMI)

This leaflet provides important information about using ABRAXANE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ABRAXANE.**

Where to find information in this leaflet:

- [1. Why am I using ABRAXANE?](#)
- [2. What should I know before I use ABRAXANE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ABRAXANE?](#)
- [5. What should I know while using ABRAXANE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ABRAXANE?

ABRAXANE contains the active ingredient paclitaxel.

ABRAXANE used to treat:

- Breast cancer
- Lung Cancer

- **Pancreatic Cancer**

ABRAXANE belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

It works by killing cancer cells and stopping them from multiplying.

2. What should I know before I use ABRAXANE?

Warnings

Do not use ABRAXANE if:

- you are allergic to paclitaxel or human albumin, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

- you have a very low white blood cell (WBC) count.
- you are pregnant or plan to become pregnant.
Like most cytotoxic medicines ABRAXANE is not recommended for use during pregnancy. If there is any need to consider this medicine during your pregnancy, your doctor will discuss with you the benefits and risks of using it.

- Males: tell your doctor if your partner plans to become pregnant while you are being treated with this medicine or shortly after you have stopped treatment with it. ABRAXANE may cause birth defects if either the male or female is being treated with it at the time of conception. It is recommended that you use some kind of birth control while you are being treated with ABRAXANE and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.
- are breastfeeding.

The active ingredient in ABRAXANE passes into breast milk and there is a possibility that your baby may be affected.

Check with your doctor if you:

- kidney disease
- liver disease. You must not be given this medicine if you have severe liver damage.
- heart problems
- any blood disorder with a reduced number of blood cells, or platelets
- any disease of the nerves
- you have an infection or high temperature. Your doctor may decide to delay your treatment until the infection is gone. A mild illness, such as a cold, is not usually a reason to delay treatment.
- lowered immunity due to diseases such as HIV/AIDS
- lowered immunity due to treatment with medicines such as cyclosporine, or other medicines used to treat cancer (including radiation therapy)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Use in children or adolescents

- The safety and effectiveness of ABRAXANE in children (under 18 years) has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and ABRAXANE may interfere with each other.

Some medicines may be affected by ABRAXANE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you are taking any of the following:

- medicines for treating infections (i.e. antibiotics such erythromycin, rifampicin, etc.; ask your doctor, nurse or pharmacist if you are unsure whether the medicine you are taking is an antibiotic), and including medicines for treating fungal infections (e.g. ketoconazole)

- medicines used to help you stabilize your mood also sometimes referred to as anti-depressants (e.g. fluoxetine)
- medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin)
- medicines used to help you lower blood lipid levels (e.g. gemfibrozil)
- medicine used for heartburn or stomach ulcers (e.g. cimetidine)
- medicines used to treat HIV and AIDS (e.g. ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine)
- a medicine called clopidogrel used to prevent blood clots.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How am I given ABRAXANE?

How ABRAXANE is given

- ABRAXANE is usually given as an infusion (drip) into a vein over 30 minutes.
- Your doctor will decide what dose of ABRAXANE you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.
- ABRAXANE may be given alone or in combination with other drugs.

- Several courses of ABRAXANE therapy may be needed depending on your response to treatment.
- Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any uncontrolled effects have been controlled.
- Ask your doctor if you want to know more about the dose of ABRAXANE you receive.

How long it will be given

Breast Cancer

ABRAXANE is usually given once every three weeks (i.e. on day 1 of a 21-day cycle). Each infusion is called one 'cycle' of chemotherapy.

Your doctor will decide how many of these cycles you will need.

Lung Cancer

ABRAXANE is given every week (i.e. on days 1, 8 and 15 of each 21-day cycle). Another medicine called carboplatin is also given on day 1 only of each 21-day cycle.

Your doctor will decide how many of these cycles you will need.

Pancreatic Cancer

ABRAXANE is given every week (i.e. on days 1, 8 and 15 of each 28-day cycle). Every 28 days is called one 'cycle' of chemotherapy. Another medicine called gemcitabine is also given on days 1, 8 and 15 after ABRAXANE has been given.

Your doctor will decide how many of these cycles you will need.

If you miss a dose

It is very important for you to keep all appointments to receive ABRAXANE. If you miss an appointment, ask your doctor when to schedule your next dose.

If you are given too much ABRAXANE

As ABRAXANE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects after being given this medicine, tell your doctor or nurse immediately. You may need urgent medical attention.

Symptoms of an ABRAXANE overdose include the side effects listed below under Section [6. Are there any side effects?](#), but are usually of a more severe nature.

5. What should I know while using ABRAXANE?

Call your doctor straight away if you:

- become pregnant while you are being treated with this medicine

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with ABRAXANE.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with this medicine. It may affect other medicines used during surgery.
- Keep all your doctor's appointments so your progress can be checked. Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.
- Keep follow-up appointments with your doctor. It is important to have your follow-up cycles of ABRAXANE at the appropriate times to get the best effects from your treatments.

Infections or bleeding

This medicine can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

The following precautions should be taken to reduce your risk of infection or bleeding:

- Avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse

throat, lower back or side pain or find it painful or difficult to urinate.

- Be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

Body fluids and waste

Your body breaks down ABRAXANE and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use

a strong solution of non-bleaching detergent and large amounts of water.

- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ABRAXANE affects you.

Some people may feel tired or dizzy after being given Abraxane. If this happens to you, do not drive or use any tools or machines.

If you are given other medication as part of your treatment, you should ask your doctor for advice on driving and using machines.

Looking after your medicine

- ABRAXANE will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place, protected from light, where the temperature stays below 25°C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

The benefits and side effects of ABRAXANE may take some time to occur. Therefore, even after you have finished receiving your treatment, you should tell your doctor immediately if you notice any of the side effects listed in this section.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● shortness of breath, coughing, wheezing or difficulty breathing● swelling of the face, lips, tongue, or other parts of the body● rash, itching or hives on the skin● extreme weakness or tiredness● seizures (fits)● fast, slow or irregular heart beat● chest pain● yellowing of the skin or eyes	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● unusual bleeding or bruising (including blood in your stools or urine) ● fever, sore throat or other signs of infection 	
<ul style="list-style-type: none"> ● pain, swelling, irritation and redness at the injection site ● flushing ● light-headedness, dizziness or fainting (due to low blood pressure) ● numbness or tingling in the fingers and/or toes ● changes in vision ● abdominal pain 	<p>Call your doctor or nurse as soon as possible</p>

Other side effects

Other side effects	What to do
<p>Very common</p> <ul style="list-style-type: none"> ● Abnormal decrease in the number of types of white blood cells (neutrophils, 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<p>lymphocytes or leukocytes) in the blood</p> <ul style="list-style-type: none"> ● Deficiency of red blood cells ● Reduction in the number of platelets in the blood ● Anorexia ● Effect on peripheral nerves (pain, numbness, tingling or loss of feeling) ● Nausea, diarrhoea, constipation, throat pain, loss of appetite ● Vomiting ● Loss of hair ● Rash ● Pain in a joint or joints ● Pain in the muscles ● Weakness and tiredness, fever <p>Common</p> <ul style="list-style-type: none"> ● Infection, including in the urinary tract, follicles, upper airways, thrush and sinuses ● Fever with decrease in the number of a 	

Other side effects	What to do
<p>type of white blood cell (neutrophils) in the blood, flushing, severe infection in your blood which may be caused by reduced white blood cells</p> <ul style="list-style-type: none"> ● Dehydration ● Decreased appetite ● Low levels of potassium in the blood ● Sleep problems ● Depression, anxiety ● Diminished muscular coordination or difficulty in reading, increased or decreased tears, loss of eyelashes ● Blurred vision ● Taste disturbance ● Headache, dizziness ● Dry mouth, difficulty in swallowing ● Muscle weakness ● Changes in heart rate or rhythm ● Decreased or increased blood pressure 	

Other side effects	What to do
<ul style="list-style-type: none"> ● Blood clot in the lungs ● Swelling of mucosal and soft tissues ● Flushing ● Difficulty in breathing ● Coughing up blood ● Nose bleeds, stuffy nose ● Chest or throat pain ● Cough ● Indigestion, abdominal discomfort or pain ● Itching, dry skin, nail disorder ● Pain in back or limb, bone pain, muscle cramps ● Weight loss ● Reduction in all blood cell counts 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ABRAXANE contains

Active ingredient (main ingredient)	paclitaxel
Other ingredients (inactive ingredients)	human albumin solution, which contains sodium, sodium octanoate and sodium acetyltryptophanate

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What ABRAXANE looks like

ABRAXANE is a white to yellow solid powder cake in a clear glass vial.

When it is reconstituted, it will be a milky liquid.

100 mg vial: AUST R 133500

250 mg vial: AUST R 297973

The 250 mg presentation is not approved by Medsafe and is therefore not marketed in New Zealand.

Who distributes ABRAXANE

Sponsor in Australia

Abraxis BioScience Australia Pty Ltd

Level 2, 4 Nexus Court

Mulgrave, VIC 3170

Australia

Telephone: 1800 CELGENE (1800 235 4363)

Distributed by Specialised Therapeutics Australia Pty Ltd

Sponsor in New Zealand

Celgene Limited

PO Box 3035

Wellington

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Telephone: 0800 526 529

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