

# PACLITAXEL ACCORD

## 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 Paclitaxel Accord?

Paclitaxel Accord contains the active ingredient paclitaxel. Paclitaxel Accord is used to treat cancer of the ovary, the breast, and non small cell cancer of the lung. Paclitaxel Accord may be used alone or in combination with other anticancer agents.

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

### 2. What should I know before I use Paclitaxel Accord?

Do not use if you are allergic to paclitaxel, other medicines similar to paclitaxel called taxanes, any of the ingredients listed at the end of this leaflet or any medicines containing PEG-35 castor oil.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I'm given Paclitaxel Accord?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Paclitaxel Accord and affect how it works.

See Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Paclitaxel Accord?

Paclitaxel Accord is an injection and will be given to you by your doctor.

More instructions can be found in Section [4. How is Paclitaxel Accord given?](#) in the full CMI.

### 5. What should I know while using Paclitaxel Accord?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any other doctors, nurses, surgeons, dentists or pharmacists who treat you that you are taking this medicine</li><li>• Tell your doctor immediately if you or your partner become pregnant while taking this medicine</li><li>• Tell your doctor if you experience any of the side effects listed in the CMI</li><li>• Keep all of your doctor's appointments so that your progress can be checked</li><li>• You should wear sun protection after receiving treatment</li></ul>
<b>Things you should not do</b>	Do not receive Paclitaxel Accord if you are allergic to paclitaxel, other medicines similar to paclitaxel called taxanes, any of the ingredients listed at the end of this leaflet or any medicines containing PEG-35 castor oil
<b>Driving or using machines</b>	Paclitaxel Accord contains absolute ethanol (alcohol) so you should not drive, operate machinery, or do anything else that could be dangerous after receiving treatment with Paclitaxel Accord.

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

### 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.

Some of the common and serious side effects are included below in the CMI. Speak to your doctor if you have side effects and they worry you.

Symptoms of a serious allergic reaction are:

- 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

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.

# PACLITAXEL ACCORD

Active ingredient: *paclitaxel*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Paclitaxel Accord. **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 Paclitaxel Accord.**

Where to find information in this leaflet:

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

## 1. Why am I using Paclitaxel Accord?

**Paclitaxel Accord contains the active ingredient paclitaxel.** Paclitaxel Accord belongs to a class of anticancer agents known as taxanes. These agents prevent the division of cells, particularly cancer cells.

Paclitaxel Accord is used to treat cancer of the ovary, the breast, and non small cell cancer of the lung. Paclitaxel Accord may be used alone or in combination with other anticancer agents.

Paclitaxel Accord is not recommended for use in children as its safety and effectiveness in patients under 18 years of age has not been established.

## 2. What should I know before I'm given Paclitaxel Accord?

### Warnings

**Do not receive Paclitaxel Accord if you have an allergy to:**

- any medicine containing paclitaxel or other medicines similar to paclitaxel called taxanes
- any of the ingredients listed at the end of this leaflet
- any medicines containing PEG-35 castor oil such as cyclosporin injection or teniposide injection

**Check with your doctor if you have or have had:**

- very low white blood cell count
- an infection or high temperature. Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment
- anaemia or suffered from other problems with your blood
- kidney or liver problems

- radiation therapy
- high or low blood pressure
- heart problems
- 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
- neuropathy (numbness, tingling and pain in feet or hands)
- serious reaction to a similar drug to paclitaxel (called taxanes)

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?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Paclitaxel Accord 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.

Male patients should seek advice regarding storage of sperm prior to treatment with paclitaxel due to the possibility of infertility.

Paclitaxel 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 paclitaxel and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Paclitaxel Accord passes into breast milk and there is a possibility that your baby may be affected.

Your doctor will discuss the risks and benefits of using Paclitaxel Accord if you are pregnant or breast-feeding.

## 3. What if I am taking other medicines?

Tell your doctor 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 Paclitaxel Accord may interfere with each other. These are:

- cisplatin and doxorubicin, medicines used to treat cancer
- erythromycin, trimethoprim and rifampicin, antibiotics used to treat some bacterial infections

- gemfibrozil, a medicine used to lower high cholesterol levels
- deferasirox, a medicine used to treat iron overload
- filgrastim, a medicine used for white blood cell disorders
- fluoxetine, a medicine used to treat depression
- carbamazepine, phenytoin and phenobarbital (phenobarbitone), medicines used for epilepsy
- efavirenz and nevirapine, medicines used to treat HIV (Human Immunodeficiency Virus) infection
- herbal medicines containing St John's wort

You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Paclitaxel Accord.**

#### 4. How is Paclitaxel Accord given?

##### How and how much will be given

Paclitaxel Accord is usually given as an infusion (drip) into a vein over 3 hours.

Paclitaxel Accord may be given alone or in combination with other drugs.

Your doctor will decide what dose of Paclitaxel Accord 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.

##### When will it be given

Before you are given Paclitaxel Accord, you must take some other medicines to prevent allergic reactions occurring during your treatment.

You will need to take dexamethasone tablets 12 hours and 6 hours before your treatment, which your doctor will prescribe for you. You will also be given 2 different injections 30 to 60 minutes prior to receiving Paclitaxel Accord. This will minimize the risk of allergic reactions occurring.

Paclitaxel Accord is usually given once every three weeks. Each infusion is called one 'cycle' of chemotherapy. Several courses of Paclitaxel Accord therapy may be needed depending on your response to treatment. Your doctor will decide how many of these cycles you will need.

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 Paclitaxel Accord you receive.

##### If too much Paclitaxel Accord is given

As your doctor will be monitoring your condition carefully, it is unlikely that you will be given too much Paclitaxel Accord. If you are concerned you have been given too much immediately telephone your doctor for advice or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

#### 5. What should I know while using Paclitaxel Accord?

##### Things you should do

Tell any other doctors, nurses, surgeons, dentists or pharmacists who treat you that you are taking this medicine.

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

Your body breaks down Paclitaxel Accord and uses it to fight cancer. The breakdown products 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, you should:

- flush the toilet twice to dispose of any body fluids and waste
- wear 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 pads in a plastic bag, seal and dispose into the garbage
- for sexual intercourse, use a barrier method such as a condom

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

You should wear sun protection after receiving treatment.

##### Driving or using machines

**Be careful driving or operating machinery until you know how Paclitaxel Accord affects you.**

Paclitaxel Accord contains absolute ethanol (alcohol) so you should not drive, operate machinery, or do anything else that could be dangerous after receiving treatment with Paclitaxel Accord.

## Looking after your medicine

The hospital will store Paclitaxel Accord under the correct conditions.

## Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Paclitaxel Accord that may be left over.

Do not use this medicine after the expiry date.

## 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.

### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>infections, including of the lungs, upper respiratory tract, inner lining of the abdomen, blood and urinary tract</li> <li>flushing and rash</li> <li>itchiness</li> <li>bone marrow suppression (primarily neutropenia)</li> <li>thrombocytopenia (reduced numbers of the white blood cells that are responsible for blood clotting)</li> <li>leucopenia (low numbers of white blood cells)</li> <li>bleeding, blood clots</li> <li>fever</li> <li>anaemia (reduced numbers of red blood cells)</li> <li>hypotension (low blood pressure)</li> <li>disturbances of heart rate and rhythm</li> <li>heart problems which can cause shortness of breath or ankle swelling</li> <li>chest pain</li> <li>increased sweating</li> <li>nausea and vomiting</li> <li>diarrhoea</li> <li>mucositis (inflammation on the lining of the mouth or throat)</li> <li>arthralgia (pain in the joints) and myalgia (muscle pain)</li> <li>peripheral neuropathy (numbness, tingling and pain in feet and hands)</li> <li>abnormal liver blood tests</li> <li>alopecia (hair loss)</li> <li>seizures and convulsions</li> <li>headache</li> </ul>	<p><b>Speak to your doctor if you have any of these common side effects and they worry you</b></p>

<ul style="list-style-type: none"> <li>visual disturbances</li> <li>hearing loss</li> <li>weight loss</li> <li>nail loss</li> <li>reactions at the injection site including localised swelling, pain, redness, hardening of the skin and skin discolouration</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>shortness of breath</li> <li>wheezing or difficulty breathing</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>rash, itching or hives on the skin</li> <li>gastrointestinal bleeding (blood in your stool)</li> <li>blistering of the skin, mouth, eyes and genitals</li> <li>fever</li> <li>chest pain</li> <li>seizures (fits)</li> <li>disturbances of heart rate and rhythm</li> <li>numbness, tingling and pain in feet and hands</li> <li>unexpected bleeding</li> <li>abdominal pain</li> <li>a reduction in certain types of blood cells in the body; a reduction in red blood cells, which may result in fatigue or dizziness; a reduction in white blood cells, which are used to fight infection; a reduction in cells that help your blood to clot after injury</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital</b></p>

**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](http://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 Paclitaxel Accord contains

<b>Active ingredient (main ingredient)</b>	paclitaxel
<b>Other ingredients (inactive ingredients)</b>	PEG-35 castor oil absolute ethanol

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

## What Paclitaxel Accord looks like

Paclitaxel Accord is a clear, colourless to slightly yellow solution supplied in a vial in packs of 1. (30 mg/5 mL: AUST R 168527, 100 mg/16.7 mL: AUST R 168525, 300 mg/50 mL: AUST R 219556).

## Who distributes Paclitaxel Accord

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne, VIC, 3000  
Australia

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