

Paclitaxel Ebewe®

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 being treated with Paclitaxel Ebewe?

Paclitaxel Ebewe contains the active ingredient paclitaxel. Paclitaxel Ebewe is used to treat ovarian cancer, breast cancer and non-small cell lung cancer (NSCLC).

For more information, see Section [1. Why am I being treated with Paclitaxel Ebewe?](#) in the full CMI.

2. What should I know before treatment with Paclitaxel Ebewe?

Do not use if you have ever had an allergic reaction to paclitaxel, other medicines similar to paclitaxel called taxanes, or any of the ingredients listed at the end of the CMI including ethanol and PEG 35 castor oil.

Talk to your doctor if you have any other medical conditions including problems with your liver, heart or nerves; lowered immunity or blood disorders; 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 treatment with Paclitaxel Ebewe?](#) in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Paclitaxel Ebewe given?

- The dose of medicine given to you will depend on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being given.

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

5. What should I know while being treated with Paclitaxel Ebewe?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are being given Paclitaxel Ebewe.• Males should use effective contraception during and for at least 4 months after stopping treatment. Females should use effective contraception while receiving this medicine and for at least 7 months after stopping treatment. If you become pregnant while you are being given Paclitaxel Ebewe, tell your doctor immediately.• Keep all your doctor's appointments so your progress can be checked.
Things you should not do	<ul style="list-style-type: none">• Do not breastfeed while you are being treated with Paclitaxel Ebewe and for 2 weeks following the last dose of treatment.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how Paclitaxel Ebewe affects you. Paclitaxel Ebewe may affect your ability to drive or operate machinery as it can cause dizziness or light-headedness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Paclitaxel Ebewe contains alcohol. Discuss drinking alcohol with your doctor.

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

6. Are there any side effects?

Side effects include flushing, light-headedness, dizziness, headache, nausea, vomiting, diarrhoea, muscle or joint pain, changes in vision, hearing loss, tinnitus, hair loss, soreness or ulceration of the mouth, pain or irritation at the injection site. Serious side effects include severe allergic reaction; signs of infection (fever, sore throat); unusual bleeding or bruising (including black stools, blood in your stools or urine); red or purple rash with blisters; fast, slow or irregular heartbeat; seizures; tingling, numbness of the skin or pins and needles sensation; severe abdominal pain; swelling and yellowing of the skin or eyeballs.

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 Ebewe®

Active ingredient(s): *paclitaxel*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being treated with Paclitaxel Ebewe?

Paclitaxel Ebewe contains the active ingredient paclitaxel. Paclitaxel Ebewe 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 growing and multiplying.

Paclitaxel Ebewe is used to treat:

- **Ovarian cancer**
- **Breast cancer**
- **Non-small cell lung cancer (NSCLC).**

2. What should I know before treatment with Paclitaxel Ebewe?

Warnings

You should not be given Paclitaxel Ebewe if:

- you are allergic to paclitaxel, other medicines similar to paclitaxel called taxanes, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have an allergy to medicines containing PEG-35 castor oil, such as ciclosporin injection.
- you have an allergy to ethanol (alcohol)
- you have a very low white blood cell (WBC) count

Check with your doctor if you have:

- any of the following medical conditions:
 - kidney disease
 - problems with your liver
 - heart problems
- lowered immunity due to:
 - diseases
 - treatment with medicines such as ciclosporin
 - other medicines/treatment used to treat cancer (including radiation therapy)
- any blood disorder with a reduced number of red blood cells, white blood cells or platelets
- any disease of the nerves or neuropathy (numbness, tingling or pain, especially in the hands and feet, or muscle weakness or problems with bladder control)
- had a previous serious reaction to a similar drug to paclitaxel (called taxanes)

You must not be given this medicine if you have a very low white blood cell (WBC) count.

Tell your doctor if you have 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.

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.

You must not be given this medicine if you are pregnant or plan to become pregnant.

Like most cytotoxic medicines Paclitaxel Ebewe 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.

Male patients should seek advice regarding storage of sperm prior to treatment with paclitaxel due to the possibility of infertility. Female patients should seek advice regarding potential fertility preservation options.

Paclitaxel Ebewe may cause birth defects if either the male or female is being treated with it at the time of conception. It is recommended that males should use effective birth control while you are being treated with Paclitaxel Ebewe and for at least 4 months after you stop using it. It is recommended for females to use effective

birth control while undergoing treatment and for at least 7 months after you stop using it. Your doctor will discuss this with you.

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

Do not breast-feed if you are taking this medicine and for 2 weeks following the last dose of treatment.

Paclitaxel Ebewe may pass into breast milk and possibly cause serious effects to your baby.

Use in the elderly

There may be a greater chance of certain problems when using Paclitaxel Ebewe. Your doctor may order extra tests and will monitor you closely.

Use in the children

Paclitaxel Ebewe is not recommended for use in children less than 18 years old.

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 may interfere with Paclitaxel Ebewe and affect how it works. These include:

- cisplatin, doxorubicin or trastuzumab, 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 Ebewe.

4. How do I use Paclitaxel Ebewe?

How much is given

Your doctor will decide what dose of Paclitaxel Ebewe 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.

Before you are given Paclitaxel Ebewe, 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 Ebewe. This will minimize the risk of allergic reactions occurring.

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

Several courses of Paclitaxel Ebewe 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.

How it is given

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

How long it will be given for

Paclitaxel Ebewe is usually given once every three weeks. Each infusion is called one 'cycle' of chemotherapy. Your doctor will decide how many of these cycles you will need.

If you are given too much Paclitaxel Ebewe

As Paclitaxel Ebewe 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 a Paclitaxel Ebewe overdose include the side effects listed below under Section [6. Are there any side effects?](#), but are usually of a more severe nature. Alert your doctor immediately if you experience redness, swelling, pain, sores, ulcers or bleeding in the mouth or throat; or any numbness, pain or unusual sensations or problems with your muscles or motor skills.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**by calling 0800 POISONS or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while I am being treated with Paclitaxel Ebewe?

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 Paclitaxel Ebewe.

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.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

Keep follow-up appointments with your doctor and have any tests as directed by your doctor.

It is important to have your follow-up cycles of Paclitaxel Ebewe at the appropriate times to get the best effects from your treatments.

Tell your doctor straight away if you have:

- shortness of breath, feel dizzy or lightheaded, experience swelling of the face, tongue, lips, mouth or throat, or itching
- a cough with shortness of breath, and chest discomfort
- severe pain on eating, drinking or swallowing, or difficulty talking due to pain
- have stomach pain or severe or persistent diarrhoea during or after treatment
- problems with vision discomfort with your infusion site at the time of treatment

Things you should not do

Do not breast-feed if you are being treated with this medicine and for 2 weeks following the last dose of treatment.

Things to be careful of

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, 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 fluids will contain Paclitaxel Ebewe and associated breakdown products for a number of days once you are given Paclitaxel Ebewe. 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 Paclitaxel Ebewe affects you.

This medicine may cause dizziness or light-headedness in some people. If you have these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Paclitaxel Ebewe contains alcohol. Discuss drinking alcohol with your doctor.

Looking after your medicine

- Paclitaxel Ebewe 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• flushing• light-headedness, dizziness, headache• nausea, vomiting• indigestion, heartburn, diarrhoea or constipation• muscle or joint pain, stiffness, swelling or reduced mobility• changes in vision• hearing loss, tinnitus• hair loss	Speak to your doctor if you have any of these serious side effects and they worry you.

<ul style="list-style-type: none"> • changes in skin or nail appearance • soreness or ulceration of the mouth • irritation and inflammation of the throat, nose or vagina • redness, tightness, cracking, flaking or peeling of the skin • thick calluses and blisters on the palms of your hands and soles of your feet • difficulty walking or using your hands • weight loss • pain, swelling, irritation, redness or discolouration at the injection site 	
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<ul style="list-style-type: none"> • blood in urine, changes to urine output, swollen ankles, fatigue 	
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Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.

Some side effects (for example, changes to blood cell counts, elevated liver enzymes, blood pressure and heart abnormalities) can only be found when your doctor does tests from time to time to check your progress.

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 or to Medsafe at <https://pophealth.my.site.com/carmreportnz/s/>. 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.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 (severe allergic reaction) • fever, sore throat or other signs of infection • tiredness, paleness, bruising or bleeding • warmth, tenderness, pain, swelling in arm or leg • rapid breathing or heart rate, confusion, fever, chills, not passing urine, discoloured skin • red or purple rash with blisters, peeling and flu like symptoms • fast, slow or irregular heartbeat including palpitations • chest discomfort or pain • dry cough, shortness of breath during exercise or at rest • oedema of legs, feet and body • increase in weight • fatigue, yellowing of the skin or eyes, abdominal pain or swelling, nausea, vomiting, dark urine, loss of appetite • seizures, fits, confusion • numbness, prickling, tingling, burning sensation on arms, legs and body • severe or persistent watery diarrhoea, with or without pus/mucus in stool • severe pain cramps, bleeding, fever, chills, bloating or swelling of abdomen 	<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>

7. Product details

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

What Paclitaxel Ebewe contains

Active ingredient (main ingredient)	paclitaxel
Other ingredients (inactive ingredients)	PEG 35 castor oil ethanol
Potential allergens	ethanol

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

What Paclitaxel Ebewe looks like

Paclitaxel Ebewe is available in four strengths:

Paclitaxel Ebewe 30 mg/ 5 mL injection – a clear to pale yellow solution, in a glass vial. Pack of 1 or 5 vials (AUST R 98548).

Paclitaxel Ebewe 100 mg/ 16.7 mL injection – a clear to pale yellow solution, in a glass vial. Pack of 1 vial (AUST R 98549).

Paclitaxel Ebewe 150 mg/ 25 mL injection – a clear to pale yellow solution, in a glass vial. Pack of 1 vial (AUST R 98550).

Paclitaxel Ebewe 300 mg/ 50 mL injection – a clear to pale yellow solution, in a glass vial. Pack of 1 vial (AUST R 98551).

Not all strengths or presentations may be marketed in Australia.

Vial stopper is not made with natural rubber latex.

Who distributes Paclitaxel Ebewe

Paclitaxel Ebewe is distributed in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Paclitaxel Ebewe is distributed in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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