

PACLITAXEL EBEWE®

paclitaxel

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Paclitaxel Ebewe. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Paclitaxel Ebewe against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Your doctor or pharmacist can provide you with more information about Paclitaxel Ebewe.

Keep this leaflet with the medicine.

You may need to read it again.

What Paclitaxel Ebewe is used for

This medicine is used to treat:

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

This medicine 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.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given Paclitaxel Ebewe

When you must not be given it

You must not be given Paclitaxel Ebewe if you have an allergy to:

- any medicine containing paclitaxel
- any of the ingredients listed at the end of this leaflet
- any medicines containing PEG-35 castor oil such as ciclosporin injection or teniposide injection

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 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 is gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

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.

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 you use some kind of birth control while you are being treated with Paclitaxel Ebewe and for at least 12 weeks after you stop using it. Your doctor will discuss this with you.

Do not breast-feed if you are taking this medicine.

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

If you are not sure whether you should be given this medicine, talk to your doctor.

The safety and effectiveness of Paclitaxel Ebewe in children has not been established.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease

- liver disease
- heart problems
- any blood disorder with a reduced number of red blood cells, white blood cells or platelets
- any disease of the nerves
- lowered immunity due to diseases such as HIV/AIDS
- lowered immunity due to treatment with medicines such as ciclosporin, or other medicines used to treat cancer (including radiation therapy)
- had a previous serious reaction to a similar drug to paclitaxel (called taxanes).

If you have not told your doctor about any of the above, tell him/her before you start treatment with Paclitaxel Ebewe.

Taking other medicines

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

Some medicines and Paclitaxel Ebewe may interfere with each other. These include:

- cisplatin, doxorubicin or trastuzumab (Herceptin), or other medicines used to treat cancer
- ketoconazole, a medicine used to treat fungal infections
- 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.

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

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

How Paclitaxel Ebewe is given

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.

Ask your doctor if you want to know more about the dose of Paclitaxel Ebewe you receive.

How it is given

Paclitaxel Ebewe is usually given as an infusion (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 take too much (overdose)

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 in the 'Side Effects' section, but are usually of a more severe nature.

If you experience severe side effects tell your doctor immediately, telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia) for advice, or go to Accident and Emergency at your nearest hospital.

While you are being given Paclitaxel Ebewe

Things you must 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 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 Paclitaxel Ebewe at the appropriate times to get the best effects from your treatments.

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.

Your body breaks down Paclitaxel Ebewe 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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Paclitaxel Ebewe.

Like other medicines that treat cancer, Paclitaxel Ebewe may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- muscle or joint pain on the arms and legs
- nausea and vomiting
- coughing
- easily tiring during physical activity
- hair loss
- indigestion, heartburn, diarrhoea or constipation
- changes in skin or nail appearance
- soreness or ulceration of the mouth.

The above list includes the more common side effects of your medicine.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- pain, swelling, irritation and redness at the injection site
- flushing
- light-headedness, dizziness or fainting (due to low blood pressure)

- headaches, confusion and memory problems
- stinging pain, numbness or tingling in the fingers and/or toes
- 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
- changes in vision
- abdominal pain
- weight loss.

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately, or if you are not in hospital, go to Accident and Emergency at your nearest hospital:

- 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
- extreme weakness or tiredness
- seizures (fits)
- fast, slow or irregular heart beat
- chest pain
- palpitations
- yellowing of the skin or eyes
- unusual bleeding or bruising (including blood in your stools or urine)
- fever, sore throat or other signs of infection.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

The benefits and side effects of Paclitaxel Ebewe 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.

After being given Paclitaxel Ebewe

Storage

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.

Product description

What it looks like

Paclitaxel Ebewe is a clear to pale yellow solution, in a glass vial.

Ingredients

Active ingredient:

Each vial of Paclitaxel Ebewe 30 mg/5 mL contains 30 mg of paclitaxel.

Each vial of Paclitaxel Ebewe 100 mg/16.7 mL contains 100 mg of paclitaxel.

Each vial of Paclitaxel Ebewe 150 mg/25 mL contains 150 mg of paclitaxel.

Each vial of Paclitaxel Ebewe 300 mg/50 mL contains 300 mg paclitaxel.

Inactive ingredient:

- PEG 35 castor oil
- ethanol.

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

Not all strengths may be marketed in Australia.

Supplier

Paclitaxel Ebewe is distributed in Australia by:

Sandoz Pty Ltd
 ABN 60 075 449 553
 54 Waterloo Road
 Macquarie Park, NSW 2113
 Australia
 Tel: 1800 726 369

Australian Register Number

Paclitaxel Ebewe 300 mg in 50 mL:
 AUST R 98551

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