

PACLITAXEL ACCORD

Paclitaxel Concentrated Injection 30 mg/5 mL, 100 mg/16.7 mL and 300 mg/50 mL

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Paclitaxel Accord.

It does not contain all the available information. It does not take the place of talking to your doctor.

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

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

Keep this leaflet.

You may need to read it again.

What Paclitaxel Accord is used for

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.

Ask your doctor if you have any questions about why Paclitaxel Accord was prescribed for you.

How Paclitaxel Accord works

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

The use of Paclitaxel Accord to treat your cancer can lead to side-effects, which are discussed below.

How Paclitaxel Accord is used

Paclitaxel Accord will be administered as an infusion in a hospital clinic. Paclitaxel Accord may be used alone or with other anticancer medicines.

The dose is worked out based on your body weight and height, and so may be different from the dose chosen for other people. Paclitaxel Accord is administered as an intravenous infusion over a 3 hour period. Administration will occur at 3 week intervals. The administration of Paclitaxel Accord requires all patients to be given premedication prior to Paclitaxel Accord.

The premedication consists of three other drugs which work by reducing the likelihood of an allergic reaction occurring when you receive your Paclitaxel Accord. They are given as tablets 12 and 6 hours before the Paclitaxel Accord is given and two injections into the vein given 30 to 60 minutes prior to the Paclitaxel Accord being given.

Before Receiving Paclitaxel Accord

When Paclitaxel Accord must not be given

- **You have a history of severe allergic reactions to paclitaxel or other drugs formulated in**

PEG-35 castor oil (Cremophor EL).

- **You have a severe neutropenia (reduced numbers of the white blood cells that fight infections)**
- **If you are pregnant or intend to become pregnant.** Paclitaxel Accord may cause harm to the unborn baby if it is given to a pregnant woman.
- **If you are breast feeding** If you take this medicine after the expiry date has passed, it may not work as well (or it may make you feel sick).

Before you receive Paclitaxel Accord

Before you receive Paclitaxel Accord for the first time you should tell your doctor if:

- If you are taking any other medicines or treatment
- If you have ever been anaemic or suffered from other problems with your blood
- If you have had kidney or liver problems
- If you have received radiation therapy
- If you have high or low blood pressure
- If you have a heart problem
- 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
- If you have ever suffered from neuropathy (numbness, tingling and pain in feet or hands)

- If you are a sexually active man. Men who receive Paclitaxel Accord are advised to use a condom to avoid pregnancy in their partner.

Receiving Paclitaxel Accord

Things you must do

- **You must tell your doctor immediately if you become pregnant while receiving Paclitaxel Accord treatment.**
- **If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with this medicine**
- **Tell all of the doctors, dentists and pharmacists who are treating you that you are receiving treatment with Paclitaxel Accord**
- **If you are about to be started on any new medicine, tell your doctor and pharmacist that you are receiving Paclitaxel Accord**
- **Have any tests recommended by your doctor done as soon as possible.**

Things to be careful of

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

If you receive too much Paclitaxel Accord (overdose)

As your dose of Paclitaxel Accord will be determined and administered by a medical specialist, the chance of receiving an overdose is most unlikely. However, if an overdose should be given your specialist will give the appropriate treatment.

Side Effects

Tell your doctor as soon as possible if you do not feel well while you are receiving Paclitaxel Accord.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Common side effects

The most common side effects include:

- Infections
- flushing and rash
- bone marrow suppression (primarily neutropenia)
- thrombocytopenia (reduced numbers of the white blood cells that are responsible for blood clotting)
- leucopenia (low numbers of white blood cells)
- bleeding
- fever
- anaemia (reduced numbers of red blood cells)
- hypotension (low blood pressure)
- nausea and vomiting
- diarrhoea
- mucositis (inflammation on the lining of the mouth or throat)
- arthralgia (pain in the joints) and myalgia (muscle pain)
- peripheral neuropathy (numbness, tingling and pain in feet and hands)
- abnormal liver blood tests
- alopecia (hair loss)

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- swelling to the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings
- gastrointestinal bleeding (blood in your stool).

Tell your doctor immediately if you notice any of the following:

- fever
- chest pain
- seizures (fits)
- disturbances of heart rate and rhythm
- numbness, tingling and pain in feet and hands
- unexpected bleeding
- abdominal pain.

The use of Paclitaxel Accord is also associated with 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.

These are serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

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 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, 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 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 break down products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to 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 towel or old rags, a strong solution of non-bleaching detergent and large amount of water to mop up 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 fluid or waste separately from other items. Use a strong solution of nonbleaching detergent and large amount of water**
- **Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into garbage.**
- **For sexual intercourse, use a barrier method such as condom.**

infusion (drip). It comes in three sizes:

30 mg Paclitaxel (5mL vials)

100 mg Paclitaxel (16.7mL vials)

300 mg Paclitaxel (50mL vials)

Ingredients

Active Ingredient: paclitaxel

Inactive Ingredients: PEG-35 castor oil and absolute ethanol.

Product is for single use in one patient only. Discard any residue.

Where to get further information

Your doctor is the best person to answer any further questions you may have about Paclitaxel Accord.

Anything your doctor tells you about Paclitaxel Accord should be followed even if it is different from what is in this leaflet.

Name and Address of the Sponsor

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

Australian Register numbers

30 mg/5 mL: AUST R 219554

100 mg/16.7 mL: AUST R 219555

300 mg/50 mL: AUST R 219556

Date of Preparation

This leaflet was prepared on 30 January 2017.

Storage

Paclitaxel Accord should be stored below 25°C. Protect from light.

Product Description

What it looks like

Paclitaxel Accord is a concentrated solution which will be diluted with a glucose solution and given as an