PACLITAXEL ACT

Paclitaxel

Consumer Medicine Information

What is in this leaflet

The medicine your doctor has prescribed for you is called PACLITAXEL ACT. The information in this leaflet will answer some questions you may have about PACLITAXEL ACT.

This leaflet does not contain everything about PACLITAXEL ACT. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

You should read this leaflet carefully before starting PACLITAXEL ACT and keep it in a safe place to refer to later.

What PACLITAXEL ACT is used for

PACLITAXEL ACT is used to treat cancer of the ovary, the breast, and non small cell cancer of the lung. PACLITAXEL ACT may be used alone or in combination with other anticancer agents. Ask your doctor if you have any questions about why PACLITAXEL ACT was prescribed for you.

How PACLITAXEL ACT works

PACLITAXEL ACT is a new class of anticancer agents known as taxanes. These agents prevent the division of cells, particularly cancer cells. The use of PACLITAXEL ACT to treat your cancer can lead to side-effects, which are discussed below.

How PACLITAXEL ACT is used

PACLITAXEL ACT will be administered in a hospital clinic. PACLITAXEL ACT may be used alone or with other anticancer medicines.

Dose
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 ACT is administered as an intravenous infusion over a 3 hour period. Administration will occur at 3 week intervals.

The administration of PACLITAXEL ACT requires all patients to be given premedication prior to PACLITAXEL ACT.

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

What you need to know before and while receiving PACLITAXEL ACT

You should always follow the advice given by your doctor. This leaflet is not a substitute for advice that your doctor tells you based on your individual circumstances.

It is important that you inform your doctor about the following:

- **If you are taking any other medicines or treatment.** Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. **Some medicines and PACLITAXEL ACT may interfere with each other.** You may need different amounts of your medicines, or you may need to take different medicines. Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being treated with this medicine.
- 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 ever suffered from neuropathy (numbness, tingling and pain in feet or hands);
- If you are or may become pregnant;
- If you are breast feeding.

You should not receive PACLITAXEL ACT if:

- You have a history of severe allergic reactions to PACLITAXEL ACT or other drugs formulated in polyoxyethylated castor oil (Cremophor® EL);
- You have a severe neutropenia (reduced numbers of the white blood cells that fight infections), before treatment with PACLITAXEL ACT.

Things to be careful of

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 ACT and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomit 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.

Be careful driving or operating machinery until you know how PACLITAXEL ACT 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

As with all prescription medicines, it is possible that PACLITAXEL ACT will cause you some unwanted side effects.

There are many side effects caused by all anticancer medicines. During PACLITAXEL ACT therapy you will require close medical supervision.

PACLITAXEL ACT can produce a variety of adverse effects, but these are generally manageable.

Serious side-effects

The most serious side-effect is anaphylaxis (sudden collapse/shock).

Another serious side-effect, and dose limiting toxicity of PACLITAXEL ACT is bone marrow suppression (fewer new blood cells are produced).

Common side-effects

The most common side-effects include:

- bone marrow suppression (primarily neutropenia)
- thrombocytopenia (reduced numbers of the white blood cells that are responsible for blood clotting),
- anaemia (reduced numbers of red blood cells),
- infections,
- hypotension (low blood pressure),
- bradycardia (slow heart beat),
- peripheral neuropathy (numbness, tingling and pain in feet and hands), myalgia (muscle pain),
- diarrhoea,
- nausea/vomiting and mucositis (inflammation of the lining of the mouth or bowel).
- Alopecia (hair loss) occurs in almost all patients.
- Elevated liver enzymes may occur.

Less Common side-effects.

Severe allergic reactions, despite premedication occur in approximately 2% of patients.

Several cases of bowel perforation have been reported.

Severe cardiac conduction abnormalities (which may result in a slowing of the heart beat) have been reported rarely.

Overdosage of the medicine

As your dose of PACLITAXEL ACT will be determined and administered by a medical specialist, the chance of receiving an overdose is most unlikely. 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 ACT overdose include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

Product Description

PACLITAXEL ACT Injection Concentrate is a clear to pale yellow solution, in a glass vial.

It comes in four sizes:

PACLITAXEL ACT 30 mg/5mL AUST R 148036

PACLITAXEL ACT 100 mg/16.67mL AUST R 148035

PACLITAXEL ACT 150 mg/25mL AUST R 148034

PACLITAXEL ACT 300 mg/50mL AUST R 148037

Active Ingredients

The active ingredient in PACLITAXEL ACT injection is 30, 100, 150, 300 mg paclitaxel per vial.

Inactive Ingredients

Inactive substances in the solution are anhydrous citric acid, PEG 35 castor oil (Cremophor® EL) and ethanol.

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

Storage of the medicine

PACLITAXEL ACT 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 deg C.

Where to get further information

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

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

Who supplies PACLITAXEL ACT

SPONSOR

Actavis Pty Ltd

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This leaflet was prepared in October 2014