

**Consumer Medicine Information****What is in this leaflet**

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

All medicines have risks and benefits. Your doctor has weighed the risks of you being given PACLITAXIN against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor or pharmacist.**

This leaflet does not contain everything about PACLITAXIN. 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 PACLITAXIN and keep it in a safe place to refer to later.**

**What PACLITAXIN is used for**

PACLITAXIN is used to treat cancer of:

- the ovary,
- the breast, and
- non-small cell cancer of the lung.

PACLITAXIN may be used alone or in combination with other anticancer agents.

**Ask your doctor if you have any questions about why PACLITAXIN was prescribed for you. Your doctor may have prescribed it for another reason.**

**How PACLITAXIN works:**

PACLITAXIN is the first of a class of anticancer agents known as taxanes. They work by killing cancer cells and stopping cancer cells from growing and multiplying.

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

**Before you are given PACLITAXIN****When you must not be given it**

**Do not use PACLITAXIN if you:**

- you have had an allergic reaction to PACLITAXEL or any of the ingredients listed at the end of this leaflet
- you have had an allergic reaction to any medication containing PEG 35 castor oil.

Some of the symptoms of an allergic reaction may include severe skin rash, itching, hives, swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing and swelling of the hands, feet or ankles.

**Do not take PACLITAXIN if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking PACLITAXIN**

**It is not known whether this medicine passes into breast milk and therefore it is**

**recommended that you stop breast-feeding.**

**Do not take PACLITAXIN if you have uncontrolled infections or low white blood cells**

**Your doctor should monitor the level of white blood cells known as neutrophils in your blood before administering treatment.**

**Before you are given PACLITAXIN**

**Tell your doctor if you have:**

- heart disease
- blood disorder
- any kind of nerve damage that causes numbness, tingling, pain, etc
- liver disease
- uncontrolled infections

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

**If you have not told your doctor about any of these things, tell them before you are given PACLITAXIN.**

**Taking other medicines**

**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 PACLITAXIN may interfere with each other. These include:

- cisplatin & doxorubicin – medicines used to treat cancer
- ketoconazole – medicine used to treat fungal infections
- Trastuzumab - used to treat breast cancer

These medicines may be affected by PACLITAXIN 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 may have more information on medicines to be careful with or avoid while being treated with this medicine.

**How PACLITAXIN is given****How much is given:**

PACLITAXIN will be administered in a hospital clinic. PACLITAXIN 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.

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

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

The premedication consists of three other drugs which work by reducing the likelihood of an allergic reaction occurring when you receive your PACLITAXIN. They are given

as tablets 12 and 6 hours before the PACLITAXIN is given and two injections into the vein given 30 to 60 minutes prior to the PACLITAXIN being given.

**While you are receiving PACLITAXIN****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 PACLITAXIN.**

**Tell all 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 being treated with this medicine, tell your doctor immediately.**

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.

**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 cell counts and other tests from time to time to check your progress and detect any unwanted side-effects.**

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 GP 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 dentist may recommend other ways to clean your teeth and gums.**

**Be careful not to cut yourself when using sharp objects such as a razor.**

**Avoid contact sports or other situations where you may bruise or get injured.**

Your body breaks down PACLITAXIN and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

You should take precautions to protect other people 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 fluids or waste. Use paper towels, a strong solution of non-bleaching detergent and large amounts of water to

mop up the spill. Discard the paper towels into a separate bag and dispose of the fluids in the toilet.

- Wash clothing and linen 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.
- Use a barrier method such as condoms for sexual intercourse.

#### **Things you must not do**

You should not receive PACLITAXIN if:

- You have a history of severe allergic reactions to PACLITAXIN or other drugs formulated in PEG 35 castor oil.
- You have a severe neutropenia (reduced numbers of the white blood cells that fight infections), before treatment with PACLITAXIN.

#### **Things to be careful of**

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

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#### **Side effects**

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

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

PACLITAXIN 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 PACLITAXIN 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), changes in nail or skin appearance.

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 PACLITAXIN 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.

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#### **Product Description**

PACLITAXIN is a concentrated solution which will be diluted with a glucose solution and given as an infusion (drip). It comes in four vial sizes in packs of 1:

30mg paclitaxel (5mL) vials (AUST R 153505)

100mg paclitaxel (16.7mL) vials (AUST R 153504)

150mg paclitaxel (25mL) vials (AUST R 153508)

300mg paclitaxel (50mL) vials (AUST R 153507)

#### **Active Ingredients**

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

#### **Inactive Ingredients**

Inactive substances in the solution are polyoxyethylated castor oil, dehydrated ethanol citric acid.

#### **Storage of the medicine**

PACLITAXIN concentrate for intravenous infusion should be stored below 25 degrees C and protected from light.

#### **Where to get further information**

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

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

Please note that knowledge about the safety of all medicines may change over time. You should discuss any problems you experience with PACLITAXIN at any time with your doctor.

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#### **Distributor**

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This leaflet was revised in July 2016