What is in this leaflet

This leaflet answers some common questions about Taxol. 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 Taxol against the benefits that are expected. This leaflet does not contain everything about Taxol. 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.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What Taxol is used for

Taxol is used to treat cancer of the ovary, the breast, and non small cell cancer of the lung. Taxol may be used alone or in combination with other anticancer medicines.

Taxol 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 Taxol was prescribed for you.

How Taxol works

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

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

How Taxol is used

Taxol will be administered as an infusion in a hospital clinic. Taxol 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. Taxol is administered as an intravenous infusion over a 3 hour period.

Administration will occur at 3 week intervals. The administration of Taxol requires all patients to be given premedication prior to Taxol.

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

Before you take Taxol

When you must not take Taxol

- You have a history of severe allergic reactions to Taxol 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), before treatment with Taxol.
- Do not take Taxol if you are pregnant or intend to become pregnant.
- If you are breast feeding
- Do not take Taxol after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

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

- 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;
- 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 Taxol are advised to use a condom to avoid pregnancy in their partner.

While you are receiving Taxol

Things you must do

- You must tell your doctor immediately if you become
pregnant while receiving Taxol treatment.

- Tell all of the doctors, dentists and pharmacists who are treating you that you are receiving treatment with Taxol.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are receiving Taxol.
- Have any tests recommended by your doctor done as soon as possible.

Things to be careful of

- Taxol contains ethanol (alcohol). You should not drive, operate machinery, or do anything else that could be dangerous after receiving treatment with Taxol.
- You should wear sun protection on your hands and feet after receiving treatment with Taxol.

If you take too much (overdose)

As your dose of Taxol 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 or pharmacist as soon as possible if you do not feel well while you are taking Taxol.

Like all medicines, it is possible that Taxol will cause you some unwanted side effects in some people. During Taxol therapy you will require close medical supervision.

The more common side effects of Taxol are:

- Infections, including of the lungs, upper respiratory tract, inner lining of the abdomen, blood and urinary tract
- Flushing and rash
- Itchiness
- 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, blood clots
- Fever
- Anaemia (reduced numbers of red blood cells)
- Hypotension (low blood pressure)
- Disturbances of heart rate and rhythm
- Heart problems which can cause shortness of breath or ankle swelling
- Chest pain
- Increased sweating
- 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)
- Seizures and convulsions
- Headache
- Visual disturbances
- Hearing loss
- Weight loss
- Nail loss
- Reactions at the injection site including localised swelling, pain, redness, hardening of the skin and skin discolouration

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 or welts
- Gastrointestinal bleeding (blood in your stool)
- Blistering of the skin, mouth, eyes and genitals

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

- Fever
- Disturbances of heart rate and rhythm
- Numbness, tingling and pain in feet and hands
- Unexpected bleeding
- Abdominal pain

The use of Taxol 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.

Product Description

Taxol is a concentrated solution which will be diluted with a saline (sodium chloride) or glucose solution and given as an intravenous infusion.

30mg paclitaxel (5mL) vials (AUST R 43924)
100mg paclitaxel (16.7mL) vials (AUST R 53248)
300mg paclitaxel (50mL) vials (AUST R 67821)
Ingredients
Active Ingredient: paclitaxel
Inactive Ingredients: PEG-35 castor oil and ethanol.

Storage
Taxol concentrate for intravenous infusion should be stored in the original carton below 25°C and protected from light.

Manufacturer
In Australia Taxol is distributed by Bristol-Myers Squibb Australia Pty Ltd
556 Princes Highway,
Noble Park,
Victoria, 3174.

Taxol is manufactured by Bristol-Myers Squibb in Italy.

Where to get further information
Your doctor is the best person to answer any further questions you may have about Taxol.
Anything your doctor tells you about Taxol should be followed even if it is different from what is in this leaflet.

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