

# TAXOL\*

Paclitaxel

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## Consumer Medicine Information

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

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.

You should read this leaflet carefully before starting *TAXOL\** and keep it in a safe place to refer to 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.

Ask your doctor if you have any questions about why *TAXOL\** was prescribed for you.

### How *TAXOL\** works

*TAXOL\** is the first of a new 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 in a hospital clinic. *TAXOL\** 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.

*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.

### What you need to know before and while receiving *TAXOL\**

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;
- \$** 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 *TAXOL*\* if:**

- \$** You have a history of severe allergic reactions to *TAXOL*\* or other drugs formulated in polyoxyethylated castor oil (Cremophor<sup>7</sup>EL);
- \$** You have a severe neutropenia (reduced numbers of the white blood cells that fight infections), before treatment with *TAXOL*\*.

**Side effects**

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

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

*TAXOL*\* 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 *TAXOL*\* 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 *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.

**Product Description:**

*TAXOL*\* is a concentrated solution which will be diluted with a glucose solution and given as an infusion (drip). It comes in four sizes:

- 30mg paclitaxel (5mL) vials (AUST R 43924)
- 100mg paclitaxel (16.7mL) vials (AUST R 53248)
- 150mg paclitaxel (25mL) vials (AUST R 53249)
- 300mg paclitaxel (50mL) vials (AUST R 67821)

**Active Ingredients:**

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

**Inactive Ingredients:**

Inactive substances in the solution are polyoxyethylated castor oil and dehydrated ethanol.

**Storage of the medicine**

*TAXOL*\* concentrate for intravenous infusion should be stored below 30°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 *TAXOL*\*.

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

**Who makes *TAXOL*\***

In Australia *TAXOL*\* is distributed by  
Bristol-Myers Squibb Pharmaceuticals a division of  
Bristol-Myers Squibb Australia Pty Ltd  
556 Princes Highway, Noble Park, Victoria, 3174.

*TAXOL*\* is manufactured by Bristol-Myers Squibb in Puerto Rico, and Bristol-Myers Squibb in Italy.

This leaflet was produced in August 2001, and reviewed in May 2004.

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

\* *TAXOL* is a trademark of Bristol-Myers Squibb Company.

**7** CREMOPHOR EL is a registered trademark of BASF Aktiengesellschaft.

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