

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

TAXOL (paclitaxel) Concentrate for infusion

TAXOL 100 (paclitaxel) Concentrate for infusion

TAXOL 300 (paclitaxel) Concentrate for infusion

Read all of this leaflet carefully before you are given TAXOL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TAXOL has been prescribed for you personally and you should not share your medicine with other people. It may harm them even if their symptoms are the same as yours.

1. WHAT TAXOL CONTAINS

The active substance is paclitaxel.

TAXOL: Each vial contains 30 mg paclitaxel.

TAXOL 100: Each vial contains 100 mg paclitaxel.

TAXOL 300: Each vial contains 300 mg paclitaxel.

The other ingredients are dehydrated alcohol (49,7 % v/v) and purified polyoxyethylated castor oil

2. WHAT TAXOL IS USED FOR

TAXOL is a cancer medicine. It is injected into a vein and it is used to treat various types of tumours. The tumours include advanced ovary and breast cancer. The tumours also include certain lung cancers (non-small cell) in people who cannot have surgery or radiation therapy.

3. BEFORE YOU ARE ADMINISTERED TAXOL

You should not be administered TAXOL:

- if you are hypersensitive (allergic) to paclitaxel or any of the other ingredients of TAXOL, especially polyoxyethylated castor oil.
- if you have dangerously low white blood cell counts.

Take special care with TAXOL:

To minimise allergic reactions, you will be given other medicines before you receive TAXOL.

Inform your doctor:

- If you experience severe allergic reactions (for example difficulty breathing, shortness of breath, chest tightness, drop in blood pressure, dizziness, lightheadedness, skin reactions such as rash or swelling).
- If you have fever, severe chills, sore throat or mouth ulcers (signs of bone marrow suppression).
- If you have numbness or weakness of the arms and legs (signs of peripheral neuropathy).
- If you have severe liver problems.
- If you have heart rhythm problems (palpitations/irregular heart beat).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

TAXOL could harm the foetus when given to a pregnant woman.

Women should not become pregnant while they are undergoing treatment with TAXOL. Tell your doctor if you become pregnant or plan to become pregnant while receiving TAXOL.

Because studies have shown TAXOL to be present in the breast milk of animals receiving the medicine it may be present in human breast milk as well. Therefore, breastfeeding a baby while using TAXOL is NOT recommended.

Driving and using machinery:

TAXOL contains alcohol. You should not drive if you feel drowsy, dizzy or are unsure of yourself.

Important information about some of the ingredients of TAXOL:

- TAXOL contains castor oil (polyoxyethylated castor oil) that may cause severe allergic reactions. If you are allergic to castor oil, talk to your doctor before you receive TAXOL.
- TAXOL contains 49,7 % v/v alcohol (dehydrated alcohol).

Using other medicines with TAXOL:

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

Interactions may occur and your doctor needs to know when using TAXOL together with:

- Cisplatin (to treat cancer). TAXOL must be administered before cisplatin.
- Doxorubicin (to treat cancer). TAXOL must be administered 24 hours after doxorubicin, to avoid high levels of doxorubicin in your body.
- Ketoconazole (to treat fungal infections). There is a possibility that the effect of TAXOL can be prolonged.

4. HOW TO RECEIVE TAXOL

Do not share medicines prescribed for you with any other person.

TAXOL is injected into a vein [intravenous (IV) infusion]. You will not be expected to give yourself TAXOL. It will be given to you by a person who is qualified to do so. Before you are given TAXOL, you will have to take certain medicines (premedications) to prevent or reduce the risk that you will have a serious allergic reaction. Such reactions have occurred and have been fatal. (See POSSIBLE SIDE EFFECTS below.)

If you receive more TAXOL than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

How to handle TAXOL intravenous solution safely

You will not handle TAXOL yourself.

5. POSSIBLE SIDE EFFECTS

TAXOL can have side effects. Most patients receiving TAXOL will experience side effects.

Not all side effects reported for TAXOL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Important side effects are described below; however, some patients may experience other side effects that are less frequent. Report any unusual symptoms to your doctor.

Tell your doctor immediately if you experience the following side effects while receiving TAXOL:

- **allergic reactions.** Allergic reactions can vary in degrees of severity. They may cause death. When a severe allergic reaction develops, it usually occurs at the time the medicine is entering the body (during TAXOL infusion). Allergic reactions may cause troubled breathing, very low blood pressure, sudden swelling, and/or hives or rash. The likelihood of a serious allergic reaction is lowered by the use of several kinds of medicines that are given to you before the TAXOL infusion.
- **heart and blood vessel (cardiovascular) effects.** TAXOL may cause a drop in heart rate (bradycardia) and low blood pressure (hypotension). The patient usually does not notice these changes. These changes usually do not require treatment. Symptoms of significant heart problems or heart failure such as difficulty breathing, feeling tired while walking, and experiencing shortness of breath that gets worse when lying flat, may occur in patients receiving TAXOL. Tell your doctor right away if you experience any of these symptoms. Your heart function, including blood pressure and pulse, will be monitored while you are receiving TAXOL. You should notify your doctor if you have a history of heart disease.
- **infections due to low white blood cell count.** Among the body's defenses against bacterial infections are white blood cells. Between your TAXOL treatment cycles, you will have blood tests to check your white blood cell counts. TAXOL usually causes a drop in white blood cells. If you have a fever or other signs of infection, tell your doctor right away. Sometimes serious infections develop that require treatment in the hospital with antibiotics. Serious illness or death could result if such infections are not treated when white blood cell counts are low.
- **irritation at the injection site.** TAXOL sometimes causes irritation at the site where it enters the vein. Reactions may include discomfort, redness, swelling, inflammation (of the surrounding skin or of the vein itself), and ulceration (open sores). These reactions are usually caused by the IV (intravenous) fluid leaking into the surrounding area. If you notice anything unusual at the site of the injection (needle), either during or after treatment, tell your doctor right away.
- **stomach upset and diarrhoea.** Some patients experience nausea, vomiting, and/or diarrhoea following TAXOL use. If you experience nausea or stomach upset, tell your doctor. Diarrhoea will usually disappear without treatment; however, if you experience severe abdominal or stomach area pain and/or severe diarrhoea, tell your doctor right away.

Tell your doctor if you notice any of the following:

- **hair loss.** Complete hair loss, or alopecia, almost always occurs with TAXOL. This usually involves the loss of eyebrows, eyelashes, and pubic hair, as well as scalp hair. It can occur suddenly after treatment has begun, but usually happens 14 to 21 days after treatment. Hair generally grows back after you've finished your TAXOL treatment.
- **joint and muscle pain.** You may get joint and muscle pain a few days after your TAXOL treatment. These symptoms usually disappear in a few days. Although pain medicine may not be necessary, tell your doctor if you are uncomfortable.
- **low red blood cell count.** Red blood cells deliver oxygen to tissues throughout all parts of the body and take carbon dioxide from the tissues by using a protein called haemoglobin. A lowering of the volume of red blood cells may occur following TAXOL treatment causing anaemia. Some patients may need a blood transfusion to treat the anaemia. Patients can feel tired, tire easily, appear pale, and become short of breath. Contact your doctor if you experience any of these symptoms following TAXOL treatment.
- **mouth or lip sores (mucositis).** Some patients develop redness and/or sores in the mouth or on the lips. These symptoms might occur a few days after the TAXOL treatment and usually decrease or disappear within one week. Talk to your doctor about proper mouth care and other ways to prevent or reduce your chances of developing mucositis.
- **numbness, tingling, or burning in the hands and/or feet (neuropathy).** These symptoms occur often with TAXOL and usually get better or go away without medication within several months of completing treatment. However, if you are uncomfortable, tell your doctor so that he/she can decide the best approach for relief of your symptoms.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF TAXOL

Store all medicines out of reach of children.

Concentrate for Intravenous Infusion: Store at or below 25 °C.

Store vials in the carton until required for use. Protect from light.

After first use any unused concentrate may be stored at or below 25 °C for up to 28 days.

Diluted solution: Solutions for infusion prepared as recommended in bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets, are stable at ambient temperature (approximately 25 °C) and lighting conditions for up to 27 hours.

Return unused medicine to the pharmacy.

Do not dispose of unused medicine in drains or sewerage systems.

7. PRESENTATION OF TAXOL

TAXOL: 30 mg/5 ml multidose vial individually packaged in a carton.

TAXOL 100: 100 mg multidose vial individually packaged in a carton.

TAXOL 300: 300 mg multidose vial individually packaged in a carton.

8. IDENTIFICATION OF TAXOL

A clear, colourless to slightly yellow viscous solution. It is supplied as a non-aqueous solution intended for dilution with a suitable parenteral fluid prior to intravenous infusion.

9. REGISTRATION NUMBER

TAXOL: 28/26/157

TAXOL 100: 31/26/107

TAXOL 300: 35/26/0196

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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