**Package leaflet: Information for the user**

**Paclitaxel 6 mg/mL concentrate for solution for infusion**
**Paclitaxel**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**


## 1. What Paclitaxel concentrate for solution for infusion is and what it is used for

Paclitaxel concentrate for solution for infusion is used in the treatment of a number of different types of cancer including ovarian cancer and breast cancer (after surgery or in advanced/spreading state) and non-small cell lung cancer (advanced state). It may be used in combination with other treatments or after other treatments have failed. It may also be used in the treatment of patients with advanced AIDS (Acquired Immuno-Deficiency Syndrome)-related Kaposi's sarcoma where previous other treatments have not been effective. Paclitaxel works by preventing the growth of certain cancer cells.

## 2. What you need to know before you use Paclitaxel concentrate for solution for infusion

**You may need to have laboratory tests (e.g. blood tests) to ensure that you can be given this medicinal product. Some patients may also need to have heart tests.**

**Do not use Paclitaxel concentrate for solution for infusion**

- If you are allergic to paclitaxel, macrogolglycerol ricinoleate (polyoxyl castor oil) or any of the other ingredients of Paclitaxel concentrate for solution for infusion
- If you are breast-feeding
- If your white blood cell or platelet count is very low (this is checked by blood tests)
- If you have a serious, uncontrolled infection and Paclitaxel is to be given for the treatment of Kaposi's sarcoma
- If you have severe liver problems

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Paclitaxel concentrate for solution for infusion

- If you notice marked allergic reaction which may cause shortness of breath, dizziness (caused by low blood pressure), swelling of the face or rash. Some of these allergic reactions can be fatal.

- If you have heart disease or liver problems (if liver damage is severe, you should not be given paclitaxel)
- If your blood cell counts are abnormal
- If you experience irregular heart beats, dizziness or faintness during treatment
- If you experience tingling, burning or numbness in your fingers and/or toes
- If this product is given to you along with radiation treatment (radiotherapy) of the lungs (see section 4 Possible side effects)
- If diarrhoea occurs during or shortly after treatment with this product as your colon could be inflamed
- If you have Kaposi's sarcoma and have a sore or inflamed mouth
- If you experience visual disturbances
- This product is not recommended for use in children under 18 years

**Other medicines and Paclitaxel concentrate for solution for infusion**

Special care should be taken if you are taking other medicinal products which could interact with paclitaxel.

Speak to your doctor when taking paclitaxel at the same time as any of the following:

- medicines for treating infections (i.e. antibiotics such as erythromycin, rifampicin, trimethoprim, etc.; ask your doctor, nurse or pharmacist if you are unsure whether the medicine you are taking is an antibiotic), and including medicines for treating fungal infections (e.g. ketoconazole)
- medicines used to treat iron overload like deferasirox
- medicines used to help you stabilize your mood also sometimes referred to as anti-depressants (e.g. fluoxetine, St. John's wort)
- medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin)
- medicines used to help you lower blood lipid levels (e.g. gemfibrozil)
- medicine used for heartburn or stomach ulcers (e.g. cimetidine)
- medicines used to treat HIV and AIDS (e.g. ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine)
- a medicine called clopidogrel used to prevent blood clots.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, it is very important that you ask your doctor for advice before taking this medicine.

<u>Pregnancy</u>

Paclitaxel concentrate for solution for infusion must not be given if you are pregnant unless clearly advised. This medicine may cause birth defects, therefore, you must not become pregnant during treatment with paclitaxel.

This medicine contains alcohol (ethanol). If you are pregnant, you should talk to your doctor or pharmacist before taking this medicine.

<u>Breast-feeding</u>

If you are breast-feeding, tell your doctor. Paclitaxel has been found in breast milk. Because of the possibility of harm to the infant, you must not breast-feed while you are treated with paclitaxel and for 2 weeks after the last dose.

This medicine contains alcohol (ethanol). If you are breast-feeding your baby, you should talk to your doctor or pharmacist before taking this medicine.

Fertility

Paclitaxel may have an anti-fertility effect which could be irreversible. If you want to have children after treatment with paclitaxel, you should talk to your doctor about your options to preserve fertility before starting the treatment.

Male patients are also advised to seek advice on conservation of sperm prior to treatment.

Contraceptive measures in men and women

If you are a woman of childbearing age, you must use effective contraceptive methods during treatment and for at least 7 months after the last dose of paclitaxel. If you become pregnant during treatment or within the 7 months after the last dose of paclitaxel, you must immediately inform your doctor.

If you are a man being treated with paclitaxel, you must use an effective method of contraception during treatment and for at least 4 months after the last dose.

**Driving and using machines**

This medicine contains an amount of alcohol (ethanol) that can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react. In addition, some side effects such as dizziness, nausea or tiredness induced by paclitaxel may also affect your ability to drive or operate machinery.

**Paclitaxel 6 mg/mL concentrate for solution for infusion contains macrogolglycerol ricinoleate (polyoxyl castor oil) and ethanol.**

This medicinal product contains macrogolglycerol ricinoleate (polyoxyl castor oil) which may cause severe allergic reactions.

This medicinal product also contains 393 mg of alcohol (ethanol) in each mL (49.7% v/v). The amount per dose of this medicine is equivalent to 650 mL beer or 260 mL wine.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

## 3. How to use Paclitaxel concentrate for solution for infusion

Your treatment will usually be given to you in hospital. Paclitaxel will be given under supervision of a doctor, who can give you more information.

Before you receive your paclitaxel injection you will be given other medicines to prevent allergic reactions (a corticosteroid, e.g. dexamethasone, an antihistamine, e.g. diphenhydramine and an $H_2$-receptor antagonist, e.g. cimetidine or ranitidine).

Paclitaxel may be given alone or in combination with other anti-cancer medicines. Your doctor will decide on the dose of product you should have and how many doses you will be given. If you are receiving combination treatment with paclitaxel and cisplatin, the paclitaxel should be administered before the cisplatin in order to reduce the possibility of side effects. If you are receiving combination treatment with paclitaxel and doxorubicin, the paclitaxel should be administered 24 hours after doxorubicin.

You will be given paclitaxel as an infusion (slow injection via a drip) into a vein. Tell your doctor or nurse at once if you notice any pain at the injection site during or shortly after treatment. Pain around the injection site could mean the needle has not been properly inserted into the vein.

The dose of paclitaxel will depend on the illness for which you are being treated, the results of your blood tests and any side effects you have had to previous doses. The dose also depends on your body surface area (expressed as $mg/m^2$) which is calculated from your height and weight. Depending on your illness, dosing is typically between 100 $mg/m^2$ and 220 $mg/m^2$ of paclitaxel given over 3 or 24 hours and repeated every two or three weeks.

As paclitaxel is most likely to be given to you in hospital, under the supervision of a doctor, it is unlikely that you will receive an incorrect dose. However if you have any concerns about the dose you receive, please tell your doctor.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, tell your doctor immediately as these are all serious. You may need urgent medical attention or hospitalisation.

Uncommon: may affect up to 1 in 100 people
- Severe chest pains possibly radiating to the jaw or arm, sweating, breathlessness and nausea (heart attack)
- Severe infection including sepsis (blood poisoning) with a state of shock
- Feeling unusually hot or cold (fever or chills)
- Blood clots in the veins (thrombosis) and inflammation of the veins associated with blood clots (thrombophlebitis) – this may present as pain and/or swelling in your arms or legs or inflammation of the vein
- Severe allergic reactions causing low or high blood pressure, chest pain, breathing problems, fast heart-beat (pulse), pain in your abdomen or extremities, sweating, severe itching and/or back pain.

Rare: may affect up to 1 in 1000 people
- Severe allergic reaction (anaphylactic reaction): you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- Shortness of breath, cough, coughing up blood or pain in the chest or shoulder (e.g. pulmonary embolism). Some of these effects may not occur immediately (lung fibrosis)

Very rare: may affect up to 1 in 10000 people
- Life-threatening allergic reaction (anaphylactic shock)

- Seizures ('fits')
- Rapid formation of a rash followed by the appearance of skin lesions on the soles of the feet and palms and ulcers in the mouth (erythema multiforme, Stevens-Johnson syndrome, epidermal necrolysis). Severe skin peeling (exfoliative dermatitis)
- Persistent diarrhoea

Tell your doctor as soon as possible if you notice any of the following:

Very common: may affect more than 1 in 10 people
- Joint or muscle weakness, pain, aching or loss of sensation in the limbs. These usually reduce or disappear several months after stopping treatment with paclitaxel
- Infection – usually of the urinary tract or upper respiratory tract. This may be associated with low blood cell count resulting from receiving Paclitaxel. This can sometimes be fatal.
- Bone marrow suppression, which can lead to decreased blood cell counts and may result in infections, anaemia with paleness and weakness, and bruising and bleeding
- Low blood pressure which may cause you to feel light-headed, particularly when standing up
- Pain in the muscle or joints
- Loss of hair (the majority of cases of hair loss happened less than one month after starting paclitaxel. When it happens, hair loss is pronounced (over 50%) in the majority of patients).
- Nausea and vomiting
- Mild diarrhoea
- Soreness of the mouth or tongue
- Mild allergic reactions including flushing and skin rash
- Nerve problems – these may appear as pins and needles in the hands and feet (can persist beyond 6 months of paclitaxel discontinuation)

Common: may affect up to 1 in 10 people
- Slow heart-beat
- Injection site reactions (local swelling, pain, redness, hardening of tissues, death of skin tissue, extravasation (leaking of drug outside the vein) resulting in cellulitis (painful swelling and redness)
- Temporary mild changes to the nails and skin
- Changes in blood tests that show how your liver is working

Uncommon: may affect up to 1 in 100 people
- Irregular heartbeats
- Fainting
- High blood pressure (may give you headaches)
- Yellowing of whites of eyes and skin
- Pain in the middle of your chest which may be caused by heart disease
- Pain or weakness in heart muscles (heart muscle degeneration)
- Irregular heartbeat (may be caused by irregular impulse conduction)
- Increased level of bilirubin in your blood, which could cause yellowing of the skin and the whites of the eyes (jaundice)

Rare: may affect up to 1 in 1000 people
- Pneumonia
- Effect on nerves that control the muscles, resulting in muscle weakness in arms and legs (motor neuropathy)
- Itching, skin rash/redness
- Accumulation of fluid in the whole body (oedema)
- Dehydration

- Loss of energy
- Problems with your lungs such as inflammation or accumulation of fluids, which may make it difficult to breathe
- Abdominal pain caused by inflammation in your bowel, bowel obstruction or perforation of the wall of your bowel
- Inflammation of your pancreas (pancreatitis)
- Heart failure
- A feeling of discomfort or uneasiness
- Increased level of creatinine in your blood

Very rare: may affect up to 1 in 10000 people
- Increased frequency of heartbeat
- Nettle rash (urticaria)
- Effect on the brain (encephalopathy)
- Damage to the liver which may be severe (hepatic necrosis). This may have an effect on brain function (hepatic encephalopathy). This can sometimes be fatal.
- Loss of hearing or ringing in the ears
- Balance problems
- Visual disturbances
- Staggering when walking
- Dizziness
- Headache
- Constipation
- Abdominal pain which may be caused by accumulation of fluid in the abdomen (ascites), inflammation in your gut or blood clot in the blood vessels to your bowel
- Loss of appetite
- Confusion
- Shock
- Loosening of finger or toe nails (you are advised to wear protection on your hands and feet when exposed to the sun)
- Heartburn, nausea and/or vomiting which may be caused by inflammation of the gullet
- Cough
- Muscle weakness, cramps, severe bowel or abdominal pain or dizziness when standing up which may be caused by a disease of the nervous system
- Acute leukaemia (blood cancer) or related condition (myelodysplastic syndrome) which your doctor will check for

Not known: frequency cannot be estimated from the available data
- A condition called tumour lysis syndrome which may cause high levels of sodium or potassium or low levels of calcium in your blood
- A swelling of part of the back of your eye (macular oedema)
- Visual disturbances such as seeing flashes of light (photopsia) or floaters
- Disease of your connective tissue (scleroderma)
- An autoimmune disorder that may affect your skin, joints, kidneys, brain, and other organs (systemic lupus erythematosus)
- A whistling sound when you breathe (wheezing)
- Disseminated intravascular coagulation, or "DIC" has been reported. This concerns a serious condition that makes people bleed too easily, get blood clots too easily, or both.
- Redness and swelling of the palms of your hands or soles of your feet which may cause your skin to peel (Palmar-plantar erythrodysesthesia syndrome)

Like many other anti-cancer medicines, paclitaxel may cause sterility, which could be permanent.

Paclitaxel may cause inflammation of the lungs when used in combination with, or after, radiotherapy.

Laboratory tests (e.g. blood tests) may be performed to check for changes in liver activity, kidney function and blood cells, which are side effects of paclitaxel treatment.

If any of the side effects gets serious, please tell your doctor.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Paclitaxel concentrate for solution for infusion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the vial label and carton. The expiry date refers to the last day of that month.

Do not store above 25 °C. Keep the vial in the outer carton, in order to protect from light.

The infusion should be clear and colourless to pale yellow. Infusions which contain clear particles or are strongly coloured should not be used.

## 6. Contents of the pack and other information

**What Paclitaxel concentrate for solution for infusion contains**
The active substance is paclitaxel. Each mL of concentrate contains 6 mg of paclitaxel.
The other ingredients are macrogolglycerol ricinoleate (polyoxyl castor oil), alcohol (ethanol) (see section 2 “Paclitaxel concentrate for solution for infusion contains alcohol (ethanol)”) and citric acid.

**What Paclitaxel concentrate for solution for infusion looks like and contents of the pack**
This medicinal product is a concentrate for solution (sterile concentrate). This means that the concentrated solution in the vial must be diluted prior to use. Once diluted it is given as a slow injection into a vein. The sterile concentrate is a clear, colourless to pale yellow solution.

This medicinal product contains 6 mg of paclitaxel per mL of concentrate. It is available in four vial sizes: 30 mg/5 mL, 100 mg/16.7 mL, 150 mg/25 mL, or 300 mg/50 mL. Each presented in packs containing a single vial. Not all presentations may be marketed.

**Marketing Authorisation Holder**

Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
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**Manufacturer**

Pfizer Service Company BV
Hermeslaan 11
1932 Zaventem
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**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

| | |
|---|---|
| Belgium: | Paclitaxel Hospira 6 mg/mL Concentraat voor oplossing voor infusie |
| Greece: | Paclitaxel Hospira πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση 6 mg/mL |
| Luxembourg: | Paclitaxel Hospira 6 mg/mL solution à diluer pour perfusion |
| United Kingdom (Northern Ireland): | Paclitaxel 6 mg/mL concentrate for solution for infusion |

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**The following information is intended for medical or healthcare professionals only:**

Further to the information included in section 3 practical information on the preparation/handling of the medicinal product is provided here.

**Instructions for use, handling and disposal**

*Handling:* Paclitaxel is a cytotoxic anticancer medicinal product and caution should be exercised in handling paclitaxel. Dilution should be carried out under aseptic conditions, by trained personnel in a designated area. Appropriate gloves should be used. Contact of paclitaxel with skin and mucous membranes should be avoided.

If paclitaxel solution contacts the skin, wash the skin immediately and thoroughly with soap and water. Following topical exposure, events have included tingling, burning, and redness. If paclitaxel contacts mucous membranes, the membranes should be flushed thoroughly with water. Upon inhalation, dyspnoea, chest pain, burning throat, and nausea have been reported.

*Protection instructions for preparation of Paclitaxel solution for infusion*
1. Protective chamber should be used and protective gloves as well as protective gown should be worn. If there is no protective chamber available, mouth cover and goggles should be used.
2. Pregnant women or women who may become pregnant, should not handle this product.
3. Opened containers, like injection vials and infusion bottles and used canules, syringes, catheters, tubes, and residuals of cytostatics should be considered as HAZARDOUS WASTE and undergo disposal according to local guidelines for the handling of HAZARDOUS WASTE.
4. Follow the instructions below in case of spillage:
- protective clothing should be worn
- broken glass should be collected and placed in the container for HAZARDOUS WASTE
- contaminated surfaces should be flushed properly with copious amounts of cold water
- the flushed surfaces should then be wiped thoroughly and the materials used for wiping should be disposed as HAZARDOUS WASTE
5. In the event of paclitaxel contact with the skin, the area should be rinsed with plenty of running water and then washed with soap and water. In case of contact with mucous membranes, wash the contacted area thoroughly with water. If you have any discomfort, contact a doctor.

6. In case of contact of paclitaxel with eyes, wash them thoroughly with plenty of cold water. Contact an ophthalmologist immediately.

*Preparation for IV Administration:* During dilution of the concentrate for infusion, cytostatic dispensing needles or similar devices with spikes should not be used with vials of paclitaxel since they can cause the stopper to collapse resulting in loss of sterile integrity of the solution.

Prior to infusion, paclitaxel must be diluted to a ready-to-use solution for infusion (0.3 to 1.2 mg/mL) using aseptic techniques with one of the following solutions:

- Sodium chloride 9 mg/mL (0.9%) solution for infusion,
- Glucose 50 mg/mL (5%) solution for infusion,
- Glucose 50 mg/mL (5%) and sodium chloride 9 mg/mL (0.9%) solution for infusion, or
- Ringer's solution containing glucose 50 mg/mL (5%).

Once diluted, the ready-to-use infusions are for single use only.

After dilution chemical and physical in-use stability has been demonstrated for:

| **Diluent** | **Target Concentration** | **Storage Conditions** | **Time period** |
|---|---|---|---|
| Sodium chloride 9 mg/mL (0.9%) solution for infusion | 0.3 mg/mL and 1.2 mg/mL | 2-8 °C in the absence of light in non-PVC (polyolefin) infusion bags | 28 days |
| Glucose 50 mg/mL (5%) solution for infusion | 0.3 mg/mL and 1.2 mg/mL | 2-8 °C in the absence of light in non-PVC (polyolefin) infusion bags | 14 days |
| Sodium chloride 9 mg/mL (0.9%) solution for infusion | 0.3 mg/mL and 1.2 mg/mL | 25 °C under normal lighting conditions in non-PVC (polyolefin) infusion bags | 72 hours |
| Glucose 50 mg/mL (5%) solution for infusion | 0.3 mg/mL and 1.2 mg/mL | 25 °C under normal lighting conditions in non-PVC (polyolefin) infusion bags | 72 hours |
| Glucose 50 mg/mL (5%) and sodium chloride 9 mg/mL (0.9%) solution for infusion | 0.3 mg/mL and 1.2 mg/mL | 25 °C under normal lighting conditions in non-PVC (polyolefin) infusion bags | 72 hours |
| Ringer's solution containing glucose 50 mg/mL (5%) | 0.3 mg/mL and 1.2 mg/mL | 25 °C under normal lighting conditions in non-PVC | 72 hours |

| | | | |
|---|---|---|---|
| | | (polyolefin) infusion bags | |

Although this product contains ethanol, it cannot be considered as assurance of microbiological integrity. From a microbiological point of view, the diluted product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

After first use and following multiple needle entries and product withdrawals, any unused concentrate maintains microbial, chemical and physical stability when stored below 25 °C, protected from light for up to 28 days. Other in-use storage times and conditions are the responsibility of the user.

The ready-to-use infusion should be visually inspected for particulate matter and discoloration.

Upon preparation, solutions may show haziness, which is attributed to the formulation vehicle, and is not removed by filtration. However haziness does not affect the potency of the product. The solution for infusion should be administered through an in-line filter with microporous membrane not greater than 0.22 microns. No significant losses in potency have been noted following simulated delivery of the solution through I.V. tubing containing an in-line (0.22 micron) filter.

There have been some reports of precipitation during paclitaxel infusions, with precipitation usually taking place towards the end of a 24-hour infusion period. To reduce the risk of precipitation, paclitaxel should be used as soon as possible after dilution and excessive shaking or agitation should be avoided. The infusion solution should be regularly inspected during infusion and the infusion should be discontinued if precipitation occurs.

To minimise patient exposure to DEHP which may be leached from plasticised PVC infusion bags, sets, or other medical instruments, diluted paclitaxel solutions should be stored in non-PVC bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets. Use of filter devices which incorporate short inlet and/or outlet plasticised PVC tubing has not resulted in significant leaching of DEHP.

*Disposal:* All items used for preparation, administration, infusion, or otherwise coming into contact with paclitaxel should be placed in an appropriate safety container and disposed according to local guidelines for the handling of cytotoxic compounds.