PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Paclitaxel 30 mg/5 ml Fresenius, Concentrate for solution for infusion

Paclitaxel 100 mg/16,7 ml Fresenius, Concentrate for solution for infusion

Paclitaxel 300 mg/50 ml Fresenius, Concentrate for solution for infusion

Paclitaxel 6 mg/ml

Read all of this leaflet carefully before you are given Paclitaxel Fresenius

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- PACLITAXEL FRESENIUS 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.

What is in this leaflet

1. What PACLITAXEL FRESENIUS is and what it is used for

2. What you need to know before you use PACLITAXEL FRESENIUS

3. How to use PACLITAXEL FRESENIUS

4. Possible side effects

5. How to store PACLITAXEL FRESENIUS

6. Contents of the pack and other information

1. What PACLITAXEL FRESENIUS is and what it is used for

Paclitaxel is an anti-cancer medicine, that inhibits the growth of cancer cells.

Paclitaxel Fresenius is used in the treatment of a number of different types of cancer:

Ovarian cancer:

- as palliative therapy (after initial surgery in combination with the platinum-containing medicine cisplatin).
- as palliative therapy after failure of other anti-cancer medicines.

Breast cancer:

- as treatment for advanced disease or disease which has spread to other parts of the body (metastatic disease). Prior treatment should have included an anthracycline (e.g. doxorubicin) (unless contraindicated).

Advanced non-small-cell lung cancer:

- as palliative treatment in patients where surgery and/or radiation therapy are not suitable.

2. What you need to know before you use PACLITAXEL FRESENIUS

PACLITAXEL FRESENIUS should not be administered to you:

- if you are allergic (hypersensitive) to paclitaxel, any of the ingredients in **Paclitaxel Fresenius** or other medicines formulated with poly-oxy-ethylated castor oil (see **What Paclitaxel Fresenius contains**);
- if you have a low white blood cell count (this is checked by blood tests);
- if you are pregnant or breastfeeding your baby;
- if you are less than 18 years of age.

Warnings and precautions

Tell your doctor or healthcare professional before being given Paclitaxel Fresenius infusion if you have:

- a heart disorder, as **Paclitaxel Fresenius** may affect your heart;
- liver problems;

- abnormal white blood cell counts;
- irregular heart beats, dizziness or faintness during treatment;
- tingling, burning or numbness in your fingers and/or toes (peripheral neuropathy).

Other medicines and PACLITAXEL FRESENIUS

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

Tell your doctor if you are receiving, or have received:

- any other cancer medicines, such as cisplatin, doxorubicin;
- ketoconazole and other similar types of antifungal medicines;
- erythromycin (an antibiotic);
- fluoxetine (an antidepressant);
- gemfibrozil (a medicine used in the treatment of high cholesterol);
- clopidogrel (a medicine used to prevent blood clots);
- cimetidine (a stomach acid reducer);
- ritonavir, saquinavir, indinavir and nelfinavir (antiviral medicines used to treat HIV);
- rifampicin (an antibiotic used for several infections, including tuberculosis (TB));
- carbamazepine, phenytoin, phenobarbital (medicines used to prevent and control seizures);
- efavirenz, nevirapine (antiviral medicines used to treat HIV).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding**,** think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving Paclitaxel Fresenius.

Pregnancy

You should not receive Paclitaxel Fresenius if you are pregnant, planning to become pregnant or think you may be pregnant.

Paclitaxel Fresenius may cause birth defects in your baby, therefore you should prevent pregnancy during treatment with Paclitaxel Fresenius.

You and/or your partner must use an effective method of contraception during your treatment with Paclitaxel Fresenius and for six months after treatment has finished. If you become pregnant during treatment, or within the six months after treatment has finished, inform your doctor immediately.

Breastfeeding

It is not known if Paclitaxel Fresenius is excreted in breastmilk. Because of the possibility of harm to the baby. You should stop breastfeeding your baby if you receive Paclitaxel Fresenius. Tell your doctor if you are breastfeeding your baby. You should not receive Paclitaxel Fresenius if you are breastfeeding your baby.

Fertility

Paclitaxel Fresenius may affect fertility, which may be permanent. If you are a male you should seek advice on conservation of sperm before treatment with Paclitaxel Fresenius.

Driving and using machines

Paclitaxel Fresenius contains alcohol which may affect your ability to drive or handle machines. Paclitaxel Fresenius causes side effects such as dizziness, a spinning or swaying movement and confusion; it may affect your ability to drive or handle machinery. You should not drive or handle machinery or tools after treatment.

Paclitaxel Fresenius contains dehydrated ethanol and macrogolglycerol ricinoleate

You should take into account the effect of the alcohol on your alertness (see also "Driving and using machines").

Paclitaxel Fresenius also contains macrogolglycerol ricinoleate (poly-oxy-ethylated castor oil), which may cause severe allergic reactions (see "Paclitaxel Fresenius should not be administered to you").

3. How to use PACLITAXEL FRESENIUS

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

You will not be expected to give yourself Paclitaxel Fresenius. It will be given to you by a person who is qualified to do so.

Since serious allergic reactions may occur, you will be treated with certain medicines (such as corticosteroids, antihistamines and antacids) before receiving Paclitaxel Fresenius.

Your doctor will decide on the correct dose and duration of the treatment based on your condition.

Tell your doctor or healthcare professional if you have pain at the injection site during treatment. He/she will check if the needle has been properly inserted into the vein.

If you have the impression that Paclitaxel Fresenius is too strong or too weak, tell your doctor or healthcare professional.

If you receive more Paclitaxel Fresenius than you should

Since a healthcare provider will administer Paclitaxel Fresenius, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage symptomatically.

If you forget to use Paclitaxel Fresenius

It is important that you keep to the schedule as determined by your doctor. Talk to your doctor if you have missed a dose of Paclitaxel Fresenius. You will not receive a double dose to make up for the forgotten dose.

4. Possible side effects

Paclitaxel Fresenius can have side effects.

Not all side effects reported for Paclitaxel Fresenius are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Paclitaxel Fresenius, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately if you notice any of the following:

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing.
- Flushing, skin reactions, rash, hives, itching, red skin, severe skin peeling.
- Rapid breathing and a change in mental status, such as reduced alertness or confusion, fever, chills, or a low body temperature may be the first signs that a serious condition (shock due to blood poisoning) is developing.
- Severe chest pains, possibly radiating to the jaw or arm, sweating, breathlessness and nausea (heart attack).
- Pain and/or swelling of the arms or legs. This may be due to blood clots in the veins (thrombosis) and inflammation in the veins associated with blood clots (thrombophlebitis).
- 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).

- Persistent watery diarrhoea, which may be bloodstained (pseudomembranous colitis).
- Yellow skin and eyes, nausea (inflammation of the pancreas or liver).
- Inability to pass stools (bowel obstruction), blood in stools, pain.

These are all very serious side effects. If you have them, you may have had a serious reaction to Paclitaxel Fresenius. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following

Frequent side effects:

- Various types of infections. This may be due to a too low white cell count; tell your doctor if you have fever, a sore throat, headaches and feel unwell.
- Low red blood cell count, low platelet count, low white blood cell count, usually only noticed with blood tests. Tell your doctor if you are tired and pale and bruise more easily than usual.
- Tingling feeling (pins and needles) in parts of the body and numbness.
- Slow heartbeat (bradycardia).
- Low blood pressure (you may feel dizzy when upright).
- Diarrhoea, nausea, vomiting.
- Stomach pain, a red and sore mouth, open sores and bleeding (inflammation of the mucous membranes).
- Hair loss.
- Muscle pain, pain in the joints of the arms and legs.
- Laboratory tests may show that liver function is affected.

Less frequent side effects:

- Pain, redness, swelling at site of injection.
- Acute leukaemia (blood cancer) or related condition (myelodysplastic syndrome) which your doctor will check for.

- Shortness of breath, weakness or feeling tired, with paler than usual skin and easy bruising or bleeding (acute myeloid leukaemia, myelodysplastic syndrome).
- Lack of appetite.
- Feeling confused.
- Seizures.
- Vision problems, seeing “floaters” or flashes of light (photopsia).
- Hearing loss, ringing in the ears, vertigo (a spinning sensation, balance problems).
- Palpitations, rapid beating of the heart, feeling faint.
- High blood pressure (usually only detected by measuring the blood pressure).
- Coughing, difficulty breathing, wheezing.
- Constipation.
- Accumulation of fluid in the bowel (ascites).
- Effect on the brain (encephalopathy).
- Pruritus, rash, skin redness (erythema).
- Nail and skin problems (including skin discolouration), loosening of finger or toenails (you should wear protection on your hands and feet when exposed to the sun).
- Laboratory tests may show that your kidney function has been affected.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PACLITAXEL FRESENIUS.

5. How to store PACLITAXEL FRESENIUS

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package in order to protect from light.
- Do not use this medicine after the expiry date stated on the container.

Discard any unused portion according to the hospital's safety rules for chemotherapeutic substances. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets or drains).

6. Contents of the pack and other information

What PACLITAXEL FRESENIUS contains

The active substance is paclitaxel 6 mg/ml.

The other ingredients are macrogolglycerol ricinoleate (poly-oxy-ethylated castor oil), citric acid, 49,7 % *v/v* dehydrated ethanol, nitrogen.

What PACLITAXEL FRESENIUS looks like and contents of the pack

Clear, slightly yellowish solution practically free from particles.

Paclitaxel 30 mg/5 ml Fresenius, with concentration 6 mg/ml is packed in a 5 ml transparent glass vial with a green flip-off cap, with a fill volume of 5 ml. Pack sizes are 1 or 5 vials per outer cardboard carton.

Paclitaxel 100 mg/16,7 ml Fresenius, with concentration 6 mg/ml is packed in a 50 ml transparent glass vial with a blue flip-off cap, with a fill volume of 16,7 ml. Pack sizes are 1 or 5 vials per outer cardboard carton.

Paclitaxel 300 mg/50 ml Fresenius, with concentration 6 mg/ml is packed in a 50 ml transparent glass vial with a purple flip-off cap, with a fill volume of 50 ml. Pack sizes are 1 or 5 vials per outer cardboard carton.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Limited

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South Africa

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Paclitaxel 30 mg/5 ml Fresenius 6 mg/ml: 43/26/0237

Paclitaxel 100 mg/16,7 ml Fresenius 6 mg/ml: 43/26/0244

Paclitaxel 300 mg/50 ml Fresenius 6 mg/ml: 43/26/0239

Access to the corresponding Professional Information

To be advised.