

APPROVED

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Paclitaxel Fresenius 6 mg/ml (30 mg/5 ml) concentrate for solution for infusion

Paclitaxel Fresenius 6 mg/ml (100 mg/16,7 ml) concentrate for solution for infusion

Paclitaxel Fresenius 6 mg/ml (300 mg/50 ml) concentrate for solution for infusion

Please read 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 PACLITAXEL FRESENIUS CONTAINS

Active ingredient:

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 IS USED FOR

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

BEFORE PACLITAXEL FRESENIUS IS ADMINISTERED TO YOU

You should not be administered Paclitaxel Fresenius, 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**);
- you have a low white blood cell count (this is checked by blood tests);
- you are pregnant or breastfeeding your baby;
- you are less than 18 years of age.

Special care should be taken with Paclitaxel Fresenius

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).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional 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, stop breastfeeding 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. Male patients are therefore advised to seek advice on conservation of sperm before treatment.

Driving and using machinery

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.

Important information about some of the ingredients of Paclitaxel Fresenius

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

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

Using other medicines with Paclitaxel Fresenius

Always tell your healthcare professional 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

HOW PACLITAXEL FRESENIUS WILL BE ADMINISTERED TO YOU

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 professional 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 missed a dose of 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.

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 toe nails (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.

STORAGE AND DISPOSAL OF 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).

PRESENTATION OF PACLITAXEL FRESENIUS

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

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

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

IDENTIFICATION OF PACLITAXEL FRESENIUS

Clear, slightly yellowish solution practically free from particles.

REGISTRATION NUMBERS

Paclitaxel Fresenius 6 mg/ml (30 mg/5 ml) 43/26/0237

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

Paclitaxel Fresenius 6 mg/ml (300 mg/50 ml) 43/26/0239

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE
CERTIFICATES OF REGISTRATION**

Fresenius Kabi South Africa (Pty) Limited

Stand 7, Growthpoint Park

2 Tonetti Street

Halfway House, 1685

South Africa

DATE OF PUBLICATION

Date of registration: 15 August 2013

Date of last approval: 3 May 2018