PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PACLITAXEL 30 VIATRIS (concentrate for dilution for infusion)

PACLITAXEL 100 VIATRIS (concentrate for dilution for infusion)

PACLITAXEL 300 VIATRIS (concentrate for dilution for infusion)

Paclitaxel

Sugar free

Read all of this leaflet carefully before you are given PACLITAXEL VIATRIS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or your~~ pharmacist, nurse or other health care provider.
- PACLITAXEL VIATRIS 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 VIATRIS is and what it is used for

PACLITAXEL VIATRIS 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. PACLITAXEL VIATRIS works by preventing the growth of certain cancer cells.

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

PACLITAXEL VIATRIS should not be administered to you:

- if you are allergic (hypersensitive) to paclitaxel, any of the ingredients in PACLITAXEL VIATRIS or other medicines formulated with polyoxyethylated castor oil (see What PACLITAXEL VIATRIS contains).
- if your white blood cell counts are abnormal (this is checked by blood tests).
- if you are pregnant or breastfeeding your baby.
- if you are a child.

Warnings and precautions

Take special care with PACLITAXEL VIATRIS:

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

Tell your doctor immediately:

- if you experience severe allergic reactions (for example difficulty breathing, shortness of breath, chest tightness, increased heartbeat, 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 experience high or low blood pressure or changes in your heart rate.

- if you have numbness or weakness of the arms and legs (signs of peripheral neuropathy).
- if you have liver problems.
- if you develop severe or persistent diarrhoea, with fever and stomach pain, during or shortly after the treatment with PACLITAXEL VIATRIS. Your colon could be inflamed (pseudomembranous colitis).
- if you experience any changes in your vision.

Children and adolescents

The safety and effectiveness of PACLITAXEL VIATRIS in children have not been established and therefore they must not receive treatment.

Other medicines and PACLITAXEL VIATRIS

Always tell your health care 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 of the following:

- 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 (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 health care provider for advice before receiving PACLITAXEL VIATRIS.

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

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

You and your partner should use effective contraception for at least 6 months after treatment with PACLITAXEL VIATRIS.

PACLITAXEL VIATRIS should not be used when you are breastfeeding. You should stop breastfeeding while you are being treated with PACLITAXEL VIATRIS. Do not restart breastfeeding until your doctor tells you it is safe to do so.

PACLITAXEL VIATRIS can cause infertility in men. If you are a male patient, speak to your doctor about freezing and storing your sperm before treatment with PACLITAXEL VIATRIS.

Driving and using machines

This medicine contains alcohol. The amount of alcohol in PACLITAXEL VIATRIS may affect your ability to drive or use machines. Therefore it may be unwise to drive immediately after a course of treatment. You should not drive or use machines if you feel dizzy or lightheaded.

It is not always possible to predict to what extent PACLITAXEL VIATRIS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PACLITAXEL VIATRIS affects you.

PACLITAXEL VIATRIS contains:

- Alcohol (dehydrated), this may be dangerous for patients suffering from alcoholism and for high-risk patients including those with liver problems or epilepsy (fits).
  The amount of alcohol in this medicine may alter the effect of other medicines.
- Polyoxyethylated castor oil which may cause severe allergic reactions.

3. How to use PACLITAXEL VIATRIS

Do not share medicines prescribed for you with any other person.
You will not be expected to give yourself PACLITAXEL VIATRIS. It will be given to you by a person who is qualified to do so and under carefully controlled conditions.

PACLITAXEL VIATRIS will be administered intravenously by your doctor or under his/her supervision. Your doctor will determine the exact dose and how many doses that you will need.
The dosage may vary according to the type of cancer that you have.
Your doctor may order that you receive premedication medicines (usually corticosteroids, antihistamines, and H_2 antagonists) prior to PACLITAXEL VIATRIS administration.

You will be given PACLITAXEL VIATRIS as an intravenous infusion (slow injection via a drip) into your vein. Tell your doctor or nurse at once if you notice any pain at the injection site during or shortly after treatment.
If you have the impression that PACLITAXEL VIATRIS is too strong or too weak, tell your doctor or health care professional.

If you receive more PACLITAXEL VIATRIS than you should:

As PACLITAXEL VIATRIS 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.

Since a health care professional will administer PACLITAXEL VIATRIS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use PACLITAXEL VIATRIS

Since a health care provider will administer PACLITAXEL VIATRIS, it is unlikely that the dose will be missed.

4. Possible side effects

PACLITAXEL VIATRIS can have side effects.

Not all side effects reported for PACLITAXEL VIATRIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PACLITAXEL VIATRIS, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately to stop treatment or go to the casualty department at your nearest hospital:

- flushing, skin reactions, 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.
- decreased or increased blood pressure, chills, back pain, chest pain, fast heartbeat, abdominal pain, pain in arms and legs, sweating.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 develop severe or persistent diarrhoea, with fever and stomach pain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infections (mainly urinary tract infections and infections in the upper respiratory tract).
- 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.
- Milder allergic (hypersensitivity) reactions such as flushing and skin rash.
- Nerve problems affecting the hands and/or feet (peripheral neuropathy), which can cause tingling feelings in the skin, numbness and/or pain.
- Slow heart beat (bradycardia).
- Low blood pressure which may cause you to feel lightheaded, particularly when standing up.
- Nausea, vomiting, diarrhoea, mucositis (sores in mouth and on lips).
- Loss of hair.
- Temporary mild changes to the nails and skin.
- Muscle or joint pain.

- Painful swelling and inflammation where the injection is given which may cause tissue hardening (occasionally cellulitis, thickening and scarring of the skin (skin fibrosis), death of skin cells (skin necrosis).
- Laboratory tests may show that liver function is affected.

Less frequent side effects:

- Shock due to infections (known as 'septic shock'), pneumonia, peritonitis, blood poisoning (sepsis).
- Shortage of white blood cells with fever and increased risk of infection (febrile neutropenia).
- Sudden disorder in blood forming cells (acute myeloid leukaemia, myelodysplastic syndrome).
- Significant allergic reactions causing low or high blood pressure, breathing problems, severe itching, back pain, chest pain, rapid beating of the heart, abdominal (tummy) pain, pain around hands and feet, and sweating).
- Serious and potentially fatal hypersensitivity reactions (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. Should this occur, seek medical attention urgently.
- Serious and potentially fatal hypersensitivity reactions with shock (anaphylactic shock).
- Loss of appetite (anorexia), dehydration.
- Confusional state.
- Effect on nerves that control the muscles, resulting in muscle weakness in arms and legs (motor neuropathy), seizures (‘fits’), convulsions, effect on the brain (encephalopathy), dizziness, headache, ataxia (irregular muscle contraction).

- Optic nerve and/or visual disturbances (scintillating scotomata).
- Loss of hearing (ototoxicity), or ringing in the ears (tinnitus), vertigo.
- Irregular heartbeat (may be caused by irregular impulse conduction), pain in the middle of your chest which may be caused by heart disease, pain or weakness in heart muscles (heart muscle degeneration), increased frequency of heartbeat, severe chest pains possibly radiating to the jaw or arm, sweating, breathlessness and nausea (heart attack).
- High blood pressure (may give you headaches), 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, shock.
- Problems with your lungs such as inflammation or accumulation of fluids, which may make it difficult to breathe, cough.
- Abdominal pain which may be caused by accumulation of fluid in the abdomen (ascites), inflammation of colon sometimes with persistent severe diarrhoea (pseudomembranous colitis), bowel obstruction, blood clot in the blood vessels to your bowel or perforation of the wall of your bowel, constipation.
- Damage to the liver which may be severe (hepatic necrosis). This may have an effect on brain function (hepatic encephalopathy).
- Itching, skin rash/redness, 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), nettle rash (urticaria), loosening of finger or toenails (you are advised to wear protection on your hands and feet when exposed to the sun).
- Pyrexia, asthenia, oedema, malaise.
- 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 VIATRIS.

5. How to store PACLITAXEL VIATRIS

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Store in original package.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

After opening before dilution: Once opened, the product may be stored for a maximum of 28 days at 25 ºC.

After dilution: Diluted infusion solutions are chemically and physically stable for 72 hours at 25 ºC. The diluted solutions should not be stored refrigerated. From a microbiological viewpoint the solution should be used immediately.

6. Contents of the pack and other information

What PACLITAXEL VIATRIS contains

The active substance is paclitaxel 6 mg/ml.

What PACLITAXEL VIATRIS looks like and contents of the pack

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

PACLITAXEL 30 VIATRIS: 8 ml multi-dose type 1 clear glass injection vial closed with a bromobutyl rubber closure and a flip-off aluminium seal individually packaged in a carton.

PACLITAXEL 100 VIATRIS: 20 ml multi-dose type 1 clear glass injection vial closed with a bromobutyl rubber closure and a flip-off aluminium seal individually packaged in a carton.

PACLITAXEL 300 VIATRIS: 50 ml multi-dose type 1 clear glass injection vial closed with a bromobutyl rubber closure and a flip-off aluminium seal individually packaged in a carton.

Holder of Certificate of Registration

Viatris South Africa (Pty) Ltd

4 Brewery Street

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1609

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