PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Sandoz Paclitaxel 30 (Concentrate for solution for Infusion)

Sandoz Paclitaxel 100 (Concentrate for solution for Infusion)

Sandoz Paclitaxel 300 (Concentrate for solution for Infusion)

Paclitaxel

Read all of this leaflet carefully before you are given SANDOZ PACLITAXEL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, nurse or other health care provider.

What is in this leaflet

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

SANDOZ PACLITAXEL belongs to the group of medicines called antineoplastics, it interferes with the growth of cancer cells, which are eventually destroyed. SANDOZ PACLITAXEL is used to treat cancer of the ovaries, breast, and certain types of lung cancer.

2. What you need to know before you are given SANDOZ PACLITAXEL

Do not receive SANDOZ PACLITAXEL

- If you are hypersensitive (allergic) to paclitaxel or any of the other ingredients (especially polyoxyl castor oil) of SANDOZ PACLITAXEL (listed in section 6).
- If you are pregnant or breastfeeding a baby.

Warnings and precautions

Tell your doctor or health care professional before being given SANDOZ PACLITAXEL:

- If you experience severe allergic reactions (for example difficulty breathing, shortness of breath, chest tightness, drop in blood pressure, dizziness, light headedness, skin reactions such as rash or swelling).
- If you have a serious heart condition or disease.
- If you have a moderate to severe liver disease.
- If you have had nerve problems in your hands or feet, such as numbness, tingling or burning (peripheral neuropathy).
- SANDOZ PACLITAXEL can temporarily lower the number of white blood cells in your blood, increasing the chance of getting an infection. It can also lower the number of platelets, which are necessary for proper blood clotting.

To minimize allergic reactions, you will be given other medicines before you receive SANDOZ PACLITAXEL.

SANDOZ PACLITAXEL should always be administered into veins. Administration of SANDOZ PACLITAXEL in the arteries can cause inflammation of the arteries, and you can suffer from pain, swelling, redness and heat. Tell your doctor immediately if any of these apply to you.

Other medicines and SANDOZ PACLITAXEL

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

If you are using any of the following substances, please tell your doctor:

- Ketoconazole (medicine to treat a fungal infection);
- Doxorubicin or trastuzumab (antineoplastics);

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 SANDOZ PACLITAXEL is administered to you.

SANDOZ PACLITAXEL should not be used during pregnancy or by women who plan to become pregnant. An effective form of birth control should be used during treatment with this product and at least six months after treatment with SANDOZ PACLITAXEL. Check with your doctor immediately if you think you have become pregnant while receiving this medicine.

If you are a male patient, you may want to seek counselling on sperm storage before starting your therapy.

SANDOZ PACLITAXEL should not be used during breastfeeding.

Driving and using machines

SANDOZ PACLITAXEL contains alcohol. Do not drive or operate any machinery directly after receiving SANDOZ PACLITAXEL.

SANDOZ PACLITAXEL contains alcohol and polyoxyl castor oil

- Alcohol (ethanol) approximately 50 % by volume, that is up to about 20 g per dose. This is equivalent to half a litre of beer per dose or a large glass (210 ml) of wine per dose. This amount 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 product may alter the effects of other medicines.
- SANDOZ PACLITAXEL contains polyoxyl castor oil (macrogolglycerol ricinoleate), which can cause severe allergic (hypersensitivity) reactions.

3. How to receive SANDOZ PACLITAXEL

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

Before you begin treatment with SANDOZ PACLITAXEL, you and your doctor should talk about the good this medicine may do as well as the risks of using it.

SANDOZ PACLITAXEL is an injection which will be administered to you by your doctor. Your doctor will mix SANDOZ PACLITAXEL with other intravenous solutions and administer it as an intravenous infusion.

The dose of SANDOZ PACLITAXEL will be different for different patients. The dose that is used may depend on a number of things, including what the medicine is being used for, the patient's size, and whether or not other medicines are also being taken.
If you have the impression that the effect of SANDOZ PACLITAXEL is too strong or too weak, talk to your doctor.

If you receive more SANDOZ PACLITAXEL than you should

Since your doctor will administer SANDOZ PACLITAXEL, he/she will control the dosage.

However, in the event of overdosage, your doctor will manage the overdosage.

If you forget to take SANDOZ PACLITAXEL

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

If you stop taking SANDOZ PACLITAXEL

Your doctor will decide when to stop treatment with SANDOZ PACLITAXEL.

4. Possible side effects

SANDOZ PACLITAXEL can have side effects.

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

Since the growth of normal body cells may also be affected by SANDOZ PACLITAXEL, other effects will also occur. Some of these may be serious and must be reported to your doctor. Other effects may not be serious but may cause concern. Some effects may not occur until months or years after the medicine is used.

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

- Shortness of breath
- Pinpoint red spots on skin
- Unusual bleeding or bruising or signs of infections such as a sore throat and high temperature

- Severe allergic 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), you may feel you are going to faint, chills, sweating, very fast heartbeat, high blood pressure, back pain, chest pain, stomach pain, pain in the limbs, pain in joints and/or inflammation of the eye (Stevens-Johnson syndrome), local peeling of the skin (epidermal necrolysis), inflammation of the skin with blisters and peeling (exfoliative dermatitis)
- Breathlessness and/or dry cough
- Increase in blood clotting, e.g. swelling, redness, pain, shortness of breath

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infections, mainly urinary tract and upper respiratory tract infections.
- An effect on the bone marrow, which can cause decreased numbers of some blood cells. This may cause anaemia.
- Tests may show a reduction of white blood cells count.
- Decreased number of blood platelets and bleeding.
- Minor allergic reactions such as flushing and rash.
- Numbness, burning or tingling in hand and feet.
- Slow heartbeat (pulse).
- Low blood pressure.
- Diarrhoea.
- Nausea and vomiting.
- Unusual hair loss or thinning.

- Mild changes in nail and skin which soon disappear.
- Pain in muscles and joints, especially in arms and legs.
- Inflammation of areas such as the lining of the mouth.
- 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)).
- Skin discolouration.
- Changes in blood tests that check how the liver is working.

Less frequent side effects:

- Shock due to infections (known as 'septic shock').
- Blood poisoning (sepsis).
- Peritonitis (inflammation in the stomach).
- Pneumonia.
- Inflammation of colon sometimes with persistent severe diarrhoea (pseudomembranous colitis).
- 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) (seen in a blood test).
- Serious and potentially fatal hypersensitivity reactions (anaphylactic reactions, anaphylactic shock).
- Loss of appetite (anorexia).
- Dehydration.
- Feeling confused.
- Affection of nerves with feeling of weakness in muscles of arms and legs (motor neuropathy).
- Seizures, fits.
- Obstruction of the intestines (paralytic ileus).

- Decreased blood pressure when standing up.
- Brain disease or brain damage (encephalopathy).
- Dizziness.
- Movement disorder (ataxia).
- Headache.
- Optic nerve and/or visual disturbances (scintillating scotomata).
- Hearing loss or reduction (ototoxicity).
- Ringing in the ears (tinnitus).
- Vertigo.
- Heart attack.
- A disorder of the electrical conduction system of the heart (atrioventricular block).
- Fainting (syncope).
- Fast or irregular heartbeat.
- Heart failure.
- High blood pressure.
- Shock.
- Low blood oxygen levels (respiratory failure).
- Blood clot in the lung.
- Lung fibrosis (a condition in which the lungs become scarred over time).
- Infection in the lungs.
- Water on the lung.
- Bowel obstruction, bowel perforation.
- Inflammation of colon (ischaemic colitis).
- Inflammation of the pancreas (pancreatitis).
- Blood clot in a blood vessel of abdomen and bowel (mesenteric thrombosis).
- **Severe inflammatory disorder of the intestines (**neutropenic colitis).
- Abnormal build-up of fluid in the abdomen (ascites).

- Inflammation or irritation of the oesophagus (oesophagitis).
- Constipation.
- Hepatic necrosis (a condition in which cells of the liver become damaged and die).
- A decline in brain function that occurs as a result of severe liver disease (hepatic encephalopathy).
- Skin rash or itching.
- Hives (urticaria).
- Loose nails.
- Fever.
- Weakness.
- Swelling.
- A feeling of general discomfort (malaise).
- Tests may show: increased bilirubin in the blood or increase in blood creatinine

The frequency of the following side effects are unknown:

- 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.
- Tumour lysis syndrome (when cancer cells die very quickly and release large amounts of potassium, phosphate, and uric acid into the blood, which can cause heart or kidney problems and lead to kidney failure).
- Blurred vision due to swelling of the retina (macular oedema).
- Seeing flashing lights or spots (photopsia).
- Hardening/thickening of the skin (sclerodema).
- Systemic lupus erythematosus (a chronic autoimmune disease mainly characterized by recurrent red patches on the skin that can cause severe fatigue and joint pain).
- *Electrocardiogram* (*ECG*) alterations (changes to your heart's rhythm).

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 SANDOZ PACLITAXEL.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store SANDOZ PACLITAXEL

- Store at room temperature not exceeding 25°C.

  After first use any unused concentrate may be stored at room temperature not exceeding 25 °C for up to 28 days.
- The concentrate for infusion is stable for 48 hours when diluted with 0,9 % sodium chloride or 5 % glucose solution to concentrations of 0,3 mg/ ml or 1,2 mg/ ml when stored at or below 25 °C.
- To be kept in outer container until required.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use the concentrate for infusion after the expiry date printed on the container or label.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What SANDOZ PACLITAXEL contains

The active substance:

Each 5 ml vial of SANDOZ PACLITAXEL 30 contains 30 mg paclitaxel, as the active ingredient.

Each 20 ml vial of SANDOZ PACLITAXEL 100 contains 100 mg paclitaxel, as the active ingredient.

Each 50 ml vial of SANDOZ PACLITAXEL 300 contains 300 mg paclitaxel, as the active ingredient.

The other ingredients are: Ethanol (anhydrous), polyoxyl castor oil (macrogolglycerol ricinoleate).

What SANDOZ PACLITAXEL looks like and contents of the pack

SANDOZ PACLITAXEL 30: Clear colourless to pale yellow solution, practically free from visible particles.

SANDOZ PACLITAXEL 100: Clear colourless to pale yellow solution, practically free from visible particles.

SANDOZ PACLITAXEL 300: Clear colourless to pale yellow solution, practically free from visible particles.

SANDOZ PACLITAXEL 30: Single 5 ml clear glass vial in a cardboard carton.

SANDOZ PACLITAXEL 100: Single 20 ml clear glass vial in a cardboard carton.

SANDOZ PACLITAXEL 300: Single 50 ml clear glass vial in a cardboard carton.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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Magwa Crescent West

Waterfall City

Jukskei View

2090

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Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07