PATIENT INFORMATION LEAFLET FOR

CIPLA-PACLITAXEL 30 / 100 / 300

SCHEDULING STATUS S4

CIPLA-PACLITAXEL 30 Concentrate for Infusion

CIPLA-PACLITAXEL 100 Concentrate for Infusion

CIPLA-PACLITAXEL 300 Concentrate for Infusion

Paclitaxel

Sugar free

Read all of this leaflet carefully before you are given CIPLA-PACLITAXEL

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

1. What CIPLA-PACLITAXEL is and what it is used for
2. What you need to know before you receive CIPLA-PACLITAXEL
3. How to receive CIPLA-PACLITAXEL
4. Possible side effects
5. How to store CIPLA-PACLITAXEL
6. Contents of the pack and other information.

1. What CIPLA-PACLITAXEL is and what it is used for

CIPLA-PACLITAXEL (Paclitaxel) belongs to a class of medicine known as Anticancer.

CIPLA-PACLITAXEL injected into a vein, and it is used to treat various types of tumours. The tumours include advanced ovary and breast cancer. The tumours also include certain lung cancers (non-small cell) in people who cannot have surgery or radiation therapy.

2. What you need to know before you receive CIPLA-PACLITAXEL

CIPLA-PACLITAXEL should not be administered to you:

- if you are hypersensitive (allergic) to Paclitaxel or any of the other ingredients of CIPLA-PACLITAXEL (listed in **section 6**).
- if you have dangerously low white blood cell counts.

Warnings and precautions

Take special care with CIPLA-PACLITAXEL

Tell your doctor or health care provider before being given the injection:

- If you experience severe allergic reactions (for example difficulty breathing, shortness of breath, chest tightness, 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 have numbness or weakness of the arms and legs (signs of peripheral neuropathy).
- If you have severe liver problems
- If you have heart rhythm problems (palpitations/irregular heart beat).

Other medicines and CIPLA-PACLITAXEL

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

CIPLA PACLITAXEL is contraindicated in:

- Patients who have a history of severe hypersensitivity reactions to CIPLA PACLITAXEL or other medicines formulated with polyoxyethylated castor oil.
- It should not be used in patients with baseline neutrophils < 1500/mm^3.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

CIPLA PACLITAXEL could harm the foetus when given to a pregnant woman.

Women should not become pregnant while they are undergoing treatment with CIPLA-PACLITAXEL. Tell your doctor if you become pregnant or plan to become pregnant while receiving CIPLA PACLITAXEL.

Because studies have shown CIPLA-PACLITAXEL to be present in the breast milk of animals receiving the medicine it may be present in human breast milk as well. Therefore, breastfeeding a baby while using CIPLA-PACLITAXEL is NOT recommended.

Driving and using machines

CIPLA-PACLITAXEL contains alcohol. You should not drive if you feel drowsy, dizzy or are unsure of yourself.

It is not always possible to predict to what extent CIPLA-PACLITAXEL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CIPLA-PACLITAXEL affects them.

CIPLA-PACLITAXEL contains

Polyoxyethylated castor oil. If you are known to be allergic (hypersensitive) to products containing polyoxyethylated castor oil, you should not receive treatment with **CIPLA-PACLITAXEL** (see **"Do not receive CIPLA-PACLITAXEL if you"**).

CIPLA-PACLITAXEL also contains dehydrated alcohol and you may experience possible brain and nervous system as well as other effects of alcohol.

3. How to receive CIPLA-PACLITAXEL

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

Always receive CIPLA-PACLITAXEL exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

CIPLA-PACLITAXEL is injected into a vein [intravenous (IV) infusion]. You will not be expected to give yourself CIPLA-PACLITAXEL. It will be given to you by a person who is qualified to do so.

Before you are given CIPLA-PACLITAXEL, you will have to take certain medicines (premedications) to prevent or reduce the risk that you will have a serious allergic reaction. Such reactions have occurred and have been fatal. (See POSSIBLE SIDE EFFECTS below.)

Your doctor will tell you how long your treatment with CIPLA-PACLITAXEL will last.

Do not stop treatment early because …

If you have the impression that the effect of CIPLA-PACLITAXEL is too strong or too weak, tell

your doctor or pharmacist.

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

If you receive more CIPLA-PACLITAXEL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to receive CIPLA-PACLITAXEL

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

4. Possible side effects

CIPLA-PACLITAXEL can have side effects.

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

Important side effects are described below; however, some patients may experience other side effects that are less frequent. Report any unusual symptoms to your doctor.

Tell your doctor immediately if you experience the following side effects while receiving CIPLA PACLITAXEL:

- allergic reactions. Allergic reactions can vary in degrees of severity. They may cause death. When a severe allergic reaction develops, it usually occurs at the time the medicine

is entering the body (during CIPLA PACLITAXEL infusion). Allergic reactions may cause troubled breathing, very low blood pressure, sudden swelling, and/or hives or rash. The likelihood of a serious allergic reaction is lowered by the use of several kinds of medicines that are given to you before the CIPLA PACLITAXEL infusion.

- heart and blood vessel (cardiovascular) effects. CIPLA PACLITAXEL may cause a drop in heart rate (bradycardia) and low blood pressure (hypotension). The patient usually does not notice these changes. These changes usually do not require treatment. Symptoms of significant heart problems or heart failure such as difficulty breathing, feeling tired while walking, and experiencing shortness of breath that gets worse when lying flat, may occur in patients receiving CIPLA PACLITAXEL. Tell your doctor right away if you experience any of these symptoms. Your heart function, including blood pressure and pulse, will be monitored while you are receiving CIPLA PACLITAXEL. You should notify your doctor if you have a history of heart disease.
- infections due to low white blood cell count. Among the body's defenses against bacterial infections are white blood cells. Between your CIPLA PACLITAXEL treatment cycles, you will have blood tests to check your white blood cell counts. CIPLA PACLITAXEL usually causes a drop in white blood cells. If you have a fever or other signs of infection, tell your doctor right away. Sometimes serious infections develop that require treatment in the hospital with antibiotics. Serious illness or death could result if such infections are not treated when white blood cell counts are low.
- irritation at the injection site. CIPLA PACLITAXEL sometimes causes irritation at the site where it enters the vein. Reactions may include discomfort, redness, swelling, inflammation (of the surrounding skin or of the vein itself), and ulceration (open sores). These reactions are usually caused by the IV (intravenous) fluid leaking into the surrounding area. If you notice anything unusual at the site of the injection (needle), either during or after treatment, tell your doctor right away.

- stomach upset and diarrhoea. Some patients experience nausea, vomiting, and/or diarrhoea following CIPLA PACLITAXEL use. If you experience nausea or stomach upset, tell your doctor. Diarrhoea will usually disappear without treatment; however, if you experience severe abdominal or stomach area pain and/or severe diarrhoea, tell your doctor right away.

Tell your doctor if you notice any of the following:

- hair loss. Complete hair loss, or alopecia, almost always occurs with CIPLA PACLITAXEL. This usually involves the loss of eyebrows, eyelashes, and pubic hair, as well as scalp hair. It can occur suddenly after treatment has begun, but usually happens 14 to 21 days after treatment. Hair generally grows back after you've finished your CIPLA PACLITAXEL treatment.
- joint and muscle pain. You may get joint and muscle pain a few days after your CIPLA PACLITAXEL treatment. These symptoms usually disappear in a few days. Although pain medicine may not be necessary, tell your doctor if you are uncomfortable.
- low red blood cell count. Red blood cells deliver oxygen to tissues throughout all parts of the body and take carbon dioxide from the tissues by using a protein called haemoglobin. A lowering of the volume of red blood cells may occur following CIPLA PACLITAXEL treatment causing anaemia. Some patients may need a blood transfusion to treat the anaemia. Patients can feel tired, tire easily, appear pale, and become short of breath. Contact your doctor if you experience any of these symptoms following CIPLA PACLITAXEL treatment.
- mouth or lip sores (mucositis). Some patients develop redness and/or sores in the mouth or on the lips. These symptoms might occur a few days after the CIPLA PACLITAXEL treatment and usually decrease or disappear within one week. Talk to your doctor about proper mouth care and other ways to prevent or reduce your chances of developing mucositis.
- numbness, tingling, or burning in the hands and/or feet (neuropathy). These symptoms occur often with CIPLA PACLITAXEL and usually get better or go away without medication within several months of completing treatment. However, if you are uncomfortable, tell your doctor so that he/she can decide the best approach for relief of your symptoms.

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 "**Adverse drug reaction and quality problem reporting form**", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/ or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of [PRODUCT NAME].

5. How to store CIPLA PACLITAXEL

Concentrate for Intravenous Infusion: Store at or below 25 °C.

Store vials in the carton until required for use. Protect from light.

After first use any unused concentrate may be stored at or below 25°C for up to 28 days.

Diluted solution: Solutions for infusion prepared as recommended in bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets, are stable at ambient temperature (approximately 25°C) and lighting conditions for up to 27 hours.

Include storage of sterile products that have been opened, diluted or reconstituted.

Discard unused portion.

Store all medicines out of reach of children.

Store in the original container.

Keep the container in the outer carton.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What CIPLA-PACLITAXEL contains

The active substance is paclitaxel. CIPLA-PACLITAXEL 30 mg/5 ml, CIPLA-PACLITAXEL 100 mg/16.7 ml, and CIPLA-PACLITAXEL 300 mg/50 ml injections contain 30 mg, 100 mg and 300 mg of paclitaxel, respectively, and 49,7% v/v dehydrated alcohol per vial.

The other ingredients in in all three formulations include polyoxyethylated castor oil and anhydrous citric acid.

What CIPLA-PACLITAXEL looks like and contents of the pack

CIPLA-PACLITAXEL 30 mg/5 ml: A clear, colourless, viscous solution, free from visible particles filled in 5 ml transparent glass single-dose vial individually packaged in a carton.

CIPLA-PACLITAXEL100 mg/16.7 ml: A clear, colourless, viscous solution, free from visible particles filled in 20 ml transparent glass single dose vial individually packaged in a carton.

CIPLA-PACLITAXEL 300 mg/50 ml: A clear, colourless, viscous solution, free from visible particles filled in 50 ml transparent glass single dose vial individually packaged in a carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER: The QR Code to be generated and included after approval.