Patient Information Leaflet for

CIPLA DOCETAXEL 20 / 80 (INJECTION)

and SOLVENT FOR CIPLA DOCETAXEL 20 / 80

SCHEDULING STATUS:

S4: CIPLA DOCETAXEL 20 and **CIPLA DOCETAXEL 80**

S1 : SOLVENT FOR CIPLA DOCETAXEL 20 and **SOLVENT FOR CIPLA DOCETAXEL 80**

CIPLA DOCETAXEL 20 (Solution for infusion)

Docetaxel 20 mg / 0,5 mL

CIPLA DOCETAXEL 80 (Solution for infusion)

Docetaxel 80 mg / 2 mL

SOLVENT FOR CIPLA DOCETAXEL 20 (Solvent for infusion)

Ethanol 13,0 % *m/v*

SOLVENT FOR CIPLA DOCETAXEL 80 (Solvent for infusion)

Ethanol 13,0 % *m/v*

Read all of this leaflet carefully before you are given CIPLA DOCETAXEL

- 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.

What is in this leaflet

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

1. What CIPLA DOCETAXEL is and what it is used for

The active substance is docetaxel. Docetaxel belongs to a class of medicines known as cytostatic agents, in other words medicines for the treatment of cancer.

CIPLA DOCETAXEL is indicated for the treatment of various cancers, including metastatic cancer (i.e. cancer that has spread to other organs) either alone or in combination with other medicines. It is indicated for the treatment of:

- Breast cancer.
- Non-small cell lung cancer.
- Ovarian cancer.
- Prostate cancer.

Your oncologist (doctor specialising in the treatment of cancer) will decide whether you qualify for treatment with CIPLA DOCETAXEL and whether or not you should receive treatment with other anticancer medicines at the same time.

The solvent is used to dissolve docetaxel.

2. What you need to know before you use CIPLA DOCETAXEL

CIPLA DOCETAXEL should not be administered to you:

- If you are hypersensitive (allergic) to docetaxel or any of the other ingredients of CIPLA DOCETAXEL (listed in **section 6**), including polysorbate 80.
- If you have neutrophil (type of white blood cell) counts below 1500 cells/mm^3. Your doctor will be able to tell you if this is so.
- If you are pregnant or breastfeeding.
- If you suffer from severe impairment of liver function.

It has not been established if CIPLA DOCETAXEL is safe to use in children.

Warnings and precautions

Take special care with CIPLA DOCETAXEL:

CIPLA DOCETAXEL should only be administered under the supervision of a qualified medical practitioner with experience in the use of anticancer medicines.

Your doctor will perform regular blood tests to evaluate the levels of your liver enzymes. Increases in the levels of liver enzymes indicate that you may be at increased risk of developing serious complications from therapy, including low white blood cell counts (white blood cells are necessary to fight infections), fever, infections, very low platelet counts, inflammation of the lips and mouth, serious skin rashes and even death.

You may become allergic or hypersensitive to CIPLA DOCETAXEL. Such reactions are characterised by shortness of breath, skin rash or very low blood pressure, and may develop within a few minutes of the start of the infusion. Your doctor may prescribe premedication to try and prevent this from happening. If you experience shortness of breath or a skin rash, please report such symptoms to your doctor as a *matter of urgency*.

Treatment with CIPLA DOCETAXEL may lead to fluid retention (keeping water back) with swelling of your feet and ankles. In severe instances fluid may accumulate in your lungs, around your heart or in your abdomen. Your doctor will monitor you for this complication and may prescribe premedication to prevent this from happening.

Treatment with CIPLA DOCETAXEL may cause damage to the nerves in your hands and feet. Symptoms of this side effect include pins and needles or pain. Some patients develop a condition in which a disagreeable sensation is produced by ordinary stimuli. Alternatively, patients may experience abnormal sensation in the absence of any stimulation. You should report any such symptoms to your doctor immediately. Your doctor may decide to stop treatment with CIPLA DOCETAXEL if these symptoms persist.

Elderly patients (older than 60 years) may be more prone to develop adverse reactions to treatment with CIPLA DOCETAXEL than younger patients.

Your doctor will also perform regular blood tests to evaluate your white blood cell counts as well as platelet counts, since treatment with CIPLA DOCETAXEL may suppress your bone marrow (where these cells are made). Bone marrow suppression may be severe and result in infection and death. White blood cells are necessary to fight infections, while platelets are essential components of blood clots.

Since treatment with CIPLA DOCETAXEL may lower your white blood cell and platelet counts, you should take the following precautions during treatment:

- Avoid people with infections, since they may pass it on to you.
- Check with your doctor immediately if you notice unusual bleeding or bruising, black tarry stools, blood in urine or stools, or pinpoint red spots on your skin.
- Be careful when using a regular toothbrush, dental floss or toothpick. Check with your doctor before you have any dental work done.
- Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime.
- Be careful not to cut yourself when you are using sharp objects, such as safety razors or fingernail or toenail cutters.
- Avoid contact sports or other situations where bruising or injury could occur.

Children

Do not give CIPLA DOCETAXEL to children, because safety has not been established.

Other medicines and CIPLA DOCETAXEL

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

In particular, tell your doctor if you are receiving:

- Any other anticancer therapy.
- Ketoconazole or itraconazole for the treatment of fungal infections.
- Ciclosporin for suppression of your immune function.
- Erythromycin, an antibiotic for the treatment of bacterial infections.
- Protease inhibitors, such as ritonavir, for the treatment of HIV-infection.

CIPLA DOCETAXEL with food and drink

No food or drink related interactions.

Pregnancy, breastfeeding and fertility:

The use of CIPLA DOCETAXEL in pregnancy and breastfeeding is not recommended, since studies in animals have shown that it may harm the developing baby. Adequate contraception to avoid pregnancy is essential during treatment and for at least three months after therapy was stopped.

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 this medicine.

Driving and using machines:

If dizziness, fatigue and weakness develop, you should exercise caution when driving or operating machinery to avoid accidents from occurring.

It is not always possible to predict to what extent CIPLA DOCETAXEL 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 DOCETAXEL affects them.

SOLVENT FOR CIPLA DOCETAXEL contains ethanol (alcohol):

SOLVENT FOR CIPLA DOCETAXEL 20 and **SOLVENT FOR CIPLA DOCETAXEL 80** contains ethanol 13 % *m/v.*

3. How to use CIPLA DOCETAXEL:

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

CIPLA DOCETAXEL is administered intravenously (into a vein). Your doctor will decide the appropriate dosage and times of administration. He/she may decide to alter your dose should you develop any side effects, such as low white cell counts or liver function abnormalities. If you suffer from liver disease, your doctor may also decide to change your dosage. Your doctor will also tell you how long treatment with CIPLA DOCETAXEL will last.

Do not stop treatment early without discussing it with your doctor. If you have the impression that the effect of CIPLA DOCETAXEL is too strong or too weak tell your treating doctor.

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

If you take more CIPLA DOCETAXEL than you should

Since a health care provider will administer CIPLA DOCETAXEL, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

If you forget to use CIPLA DOCETAXEL

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

If you stop using CIPLA DOCETAXEL

Not applicable.

4. Possible side effects

CIPLA DOCETAXEL can have side effects.

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

One of the most common, and potentially most serious, side effects associated with CIPLA DOCETAXEL therapy is low white blood cell counts. White blood cells are necessary to maintain a healthy immune system and to fight infections. You should immediately report to your doctor if you develop fever or chills, cough or hoarseness, lower back or flank pain, painful or difficult urination or a sore throat.

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

- Allergic or hypersensitivity reactions, presenting with swelling of the face, lips, or throat, skin rash or hives, fever or chills, and difficulty breathing, or shortness of breath.
- Skin rash, with or without itching.
- Blisters on the skin.
- Convulsions or loss of consciousness

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

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

- Fever.

- Low red blood cell counts (presenting with tiredness or shortness of breath) and low platelet counts (presenting with easy bruising, bleeding from the gums, or pinpoint red spots on your skin).
- Chest pain radiating into the arm or jaw, or palpitations.
- Pain and/or swelling of your calve muscles, as this may indicate a blood clot in your calve muscle.
- Swelling of the feet and ankles or weight gain due to the retention of fluid.
- Shortness of breath or troubled breathing.
- Severe abdominal pain accompanied by swelling of the abdomen, loss of appetite, or nausea, and fever.
- Severe diarrhoea with stomach cramping, or blood in the stool.
- Inability to pass stool accompanied by stomach distension, nausea and vomiting, and severe cramping.
- Jaundice, a yellow discolouration of the skin or whites of the eyes, due to liver damage.

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:

- Pins and needles, or abnormal (unpleasant) sensation with normal stimulation, or pain.
- Weakness.
- Visual disturbances, including light flashes.
- Lung disorders, such as coughing, or nose bleeds.

- Gut disorders, such as nausea, vomiting, diarrhoea, stomach pain, loss of appetite and constipation. Inflammation of the lips or mouth, inflammation of the oesophagus, or abnormal taste may also develop.
- Hair loss (frequently), itching, discolouration of the nails, loosening of the nails, and bruising or redness at the injection site.
- Weakness and generally feeling unwell.
- Muscle or joint pain.
- Tearing of the eyes.
- Menstrual disturbances.

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 or 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 CIPLA DOCETAXEL.

5. How to store CIPLA DOCETAXEL:

Store all medicines out of reach of children

Unopened vials

Unopened vials (including solvent vials) should be stored between 2 °C and 8 °C, protected from bright light. Freezing does not adversely affect the product.

The centre where you receive your treatment will store and dispose of CIPLA DOCETAXEL on your behalf.

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 DOCETAXEL contains

The active substance is docetaxel.
Each vial of CIPLA DOCETAXEL 20 contains docetaxel trihydrate equivalent to 20 mg doxetaxel (anhydrous) in 0,5 mL polysorbate 80.
Each vial of CIPLA DOCETAXEL 80 contains docetaxel trihydrate equivalent to 80 mg doxetaxel (anhydrous) in 2,0 mL polysorbate 80.

The inactive ingredients include anhydrous citric acid and polysorbate 80.

Each vial of SOLVENT FOR CIPLA DOCETAXEL 20 contains 13,0 % m/v ethanol 95 % v/v.
Each vial of SOLVENT FOR CIPLA DOCETAXEL 80 contains 13,0 % m/v ethanol 95 % v/v.

What CIPLA DOCETAXEL looks like and contents of the pack

CIPLA DOCETAXEL 20: A light yellow viscous clear solution in a 5 mL glass vial.

CIPLA DOCETAXEL 80: A light yellow viscous clear solution in a 15 mL glass vial.

CIPLA DOCETAXEL 20 and CIPLA DOCETAXEL 80 are available in cartons containing transparent glass vials of either CIPLA DOCETAXEL 20 or CIPLA DOCETAXEL 80.

SOLVENT FOR CIPLA DOCETAXEL 20:

A clear colourless solution packed in transparent glass vial with a grey butyl stopper and a red opaque aluminium flip-off seal.

SOLVENT FOR CIPLA DOCETAXEL 80:

A clear colourless solution packed in transparent glass vial with a grey butyl stopper and a serulin blue aluminium flip-off seal.

SOLVENT FOR CIPLA DOCETAXEL 20 is packed in a carton in a 5 mL vial containing 1,5 mL solvent.

SOLVENT FOR CIPLA DOCETAXEL 80 is packed in a carton in a 15 mL vial containing 61,0 mL solvent.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

This leaflet was last revised

09 August 2019

Registration number

CIPLA DOCETAXEL 20: 41/26/0162

CIPLA DOCETAXEL 80: 41/26/0163

SOLVENT FOR CIPLA DOCETAXEL 20 INJECTION: 44/32.2/0393

SOLVENT FOR CIPLA DOCETAXEL 80 INJECTION: 44/32.2/0394