

**Patient Information Leaflet**  
**Information for the Patient about**  
**CIPLA-DOCETAXEL 20 / 80 INJECTION**

**Read this entire leaflet carefully before you receive CIPLA-DOCETAXEL.**

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**

**SCHEDULING STATUS:**

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

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

**PROPRIETARY NAME (AND DOSAGE FORM):**

**CIPLA-DOCETAXEL 20** (Solution for infusion)

**CIPLA-DOCETAXEL 80** (Solution for infusion)

**SOLVENT FOR CIPLA-DOCETAXEL 20 INJECTION** (Solvent)

**SOLVENT FOR CIPLA-DOCETAXEL 80 INJECTION** (Solvent)

**WHAT CIPLA-DOCETAXEL CONTAINS:**

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.

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 INJECTION** contains 13,0 % m/v ethanol 95 % v/v.

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

#### **WHAT CIPLA-DOCETAXEL IS USED FOR:**

**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.

**BEFORE YOU RECEIVE CIPLA-DOCETAXEL:**

**Do NOT receive CIPLA-DOCETAXEL if you:**

- Are known to be hypersensitive (allergic) to **CIPLA-DOCETAXEL**, or to any components of the formulation, including polysorbate 80.
- Have neutrophil (type of white blood cell) counts below 1500 cells/mm<sup>3</sup>.  
Your doctor will be able to tell you if this is so.
- Are pregnant or breastfeeding.
- Suffer from severe impairment of liver function.

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

**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 mean time.
- 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.

**Use in pregnancy and breastfeeding:**

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 your baby while receiving CIPLA-DOCETAXEL, please consult your doctor, pharmacist or other healthcare professional for advice.**

**Driving and using machinery:**

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

**Taking other medicines with CIPLA-DOCETAXEL:**

**If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CIPLA-DOCETAXEL with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.**

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.

### **HOW CIPLA-DOCETAXEL WILL BE ADMINISTERED TO YOU:**

**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.

If you have the impression that **CIPLA-DOCETAXEL** is too strong or too weak for you, please discuss this with your treating doctor.

### **POSSIBLE SIDE-EFFECTS:**

#### **CIPLA-DOCETAXEL can have side-effects.**

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.

Other serious side-effects, which you should report to your doctor as a matter of urgency, include:

- 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.
- 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.
- Blisters on the skin.
- Convulsions or loss of consciousness.

Other potentially serious side-effects, which you should report to your doctor as soon as possible, include:

- Pins and needles, or abnormal (unpleasant) sensation with normal stimulation, or pain.
- Weakness.
- Skin rash, with or without itching.
- Visual disturbances, including light flashes.

Other side-effects with **CIPLA-DOCETAXEL**, which you should report to your doctor if they continue or become bothersome, include:

- 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.

**Not all side-effects reported for CIPLA-DOCETAXEL are included in this leaflet. Should your general health worsen while receiving CIPLA-DOCETAXEL, please consult your doctor, pharmacist or other healthcare professional for advice.**

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**STORAGE AND DISPOSING OF CIPLA-DOCETAXEL:**

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

**PRESENTATION OF CIPLA-DOCETAXEL:**

**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 INJECTION** is packed in a carton in a 5 ml vial containing 1,5 ml solvent.

**SOLVENT FOR CIPLA-DOCETAXEL 80 INJECTION** is packed in a carton in a 15 ml vial containing 61,0 ml solvent.

**IDENTIFICATION OF CIPLA-DOCETAXEL:**

**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.

**SOLVENT FOR CIPLA-DOCETAXEL 20 INJECTION:**

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 INJECTION:**

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

**REGISTRATION NUMBERS:**

**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

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

**CERTIFICATES OF REGISTRATION:**

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

**DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:**

04 March 2011