Proposed Patient Information Leaflet

Information for the Patient about

CIPLA-TEICOPLANIN 200 / 400

Read this entire leaflet carefully before you receive CIPLA-TEICOPLANIN.

- **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

PROPRIETARY NAME (AND DOSAGE FORM):

CIPLA-TEICOPLANIN 200 (**Lyophilised** Powder for Solution for Infusion)

CIPLA-TEICOPLANIN 400 (**Lyophilised** Powder for Solution for Infusion)

WHAT CIPLA-TEICOPLANIN CONTAINS:

CIPLA-TEICOPLANIN 200 contains 200 mg of teicoplanin.

CIPLA-TEICOPLANIN 400 contains 400 mg of teicoplanin.

Teicoplanin is an antibiotic.

The inactive ingredient in the formulations is sodium chloride.

The injection will be mixed with 3 ml of water for injection prior to administration.

WHAT CIPLA-TEICOPLANIN IS USED FOR:

CIPLA-TEICOPLANIN is an antibiotic. It is used to treat infections caused by bacteria sensitive (susceptible) to teicoplanin.

It is specifically used to treat infections of:

- The heart valves.
- Bone.
- Skin and soft tissues.
- Kidney or bladder.
- The lining of the abdominal (stomach) cavity, known as peritonitis, associated with peritoneal dialysis.

CIPLA-TEICOPLANIN is also indicated for the treatment of blood-borne infections (blood poisoning or septicaemia).

CIPLA-TEICOPLANIN can also used before operations (surgery) to prevent infections.

BEFORE YOU TAKE CIPLA-TEICOPLANIN:

Do NOT take CIPLA-TEICOPLANIN if you:

- Are allergic (hypersensitive) to teicoplanin or any of the other ingredients in **CIPLA-TEICOPLANIN**.
- Are pregnant or breast feeding (see **"Pregnancy and breast feeding"**).

CIPLA-TEICOPLANIN cannot be used in children younger than three years old.

Take special care with CIPLA-TEICOPLANIN:

Tell your doctor if any of the following applies to you as you may require a lower dose or special monitoring:

- You are allergic to the antibiotic called vancomycin.

- You have kidney problems.
- You are using any of the following medicines:
    - Antibiotics, such as aminoglycosides or colistin.
    - Antifungal agents, such as amphotericin B.
    - Cyclosporine, a medicine that suppresses the immune system in patients who received organ transplants.
    - Cisplatin for the treatment of cancer.
    - Water tablets (diuretics), for example furosemide or ethacrynic acid.

During therapy with **CIPLA-TEICOPLANIN** your doctor may have to perform blood tests to monitor your platelet counts. Platelets play an important role in blood clotting. You may also require periodic blood tests for blood cell counts and for liver function tests.

It may also be necessary to perform blood tests to evaluate your kidney function, especially if you will be using **CIPLA-TEICOPLANIN** over the long-term, if you already have impairment of kidney function, or if you are using other medicines that may influence kidney function. Your doctor may also ask you to go for hearing assessments, especially if you are using other medicines that may cause hearing loss or reduce the function of your kidneys.

Pregnancy and breast feeding:

The use of **CIPLA-TEICOPLANIN** in women who are pregnant or breast feeding is contra-indicated.

If you are pregnant or breast feeding your baby while taking CIPLA-TEICOPLANIN, please consult your doctor, pharmacist or other healthcare professional for advice.

Taking other medicines with CIPLA-TEICOPLANIN:

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

In particular, check with your doctor if you are taking any of the following, as concurrent or sequential use with these medicines may cause damage to your kidneys or nerves:

- Medicines for infections (such as aminoglycoside antibiotics) or other antibiotics (such as colistin).
- Medicines for fungal infections (such as amphotericin B).
- Cyclosporine – used in transplant surgery and in painful joint and skin diseases.
- Cisplatin – used to treat some cancers.
- Water tablets (diuretics) such as furosemide and ethacrynic acid.

(See **"Take special care with CIPLA-TEICOPLANIN"**.)

HOW TO RECEIVE CIPLA-TEICOPLANIN:

CIPLA-TEICOPLANIN will be administered into your veins or into a muscle in a dosage calculated by your treating doctor. The length of treatment will be determined by the type and severity of your infection. Your doctor will decide how long treatment with **CIPLA-TEICOPLANIN** will last. Treatment usually does not last for more than 4 months and should be continued for at least three days after you have become free from fever and all your symptoms have disappeared.

Your doctor may decide to change your dosage if you suffer from kidney problems.

If you have the impression that the effect of **CIPLA-TEICOPLANIN** is too strong or too weak for you, talk to your doctor or pharmacist.

POSSIBLE SIDE-EFFECTS:

CIPLA-TEICOPLANIN can have side effects.

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

Serious side-effects that you should report to your doctor as a matter of urgency include:

- Skin rash, swelling of the face or body, shortness of breath or difficulty breathing and/or generalised itching, as this may indicate an allergic reaction.

- Blistering of the skin, mouth, eyes or genitals. This may indicate serious conditions known as “Steven-Johnsons syndrome” or “toxic epidermal necrolysis”.
- Shortness of breath or difficulty breathing.
- Any hearing loss, ringing or buzzing in the ears or feeling dizzy or off-balance.
- Inability to pass urine or difficulty to pass urine accompanied by swelling, tiredness and generally feeling unwell as this may indicate poor function of your kidneys.
- Pinpoint red spots on the skin, easy bruising or bleeding from the gums, as this may be due to low platelet counts.
- Fever, chills, coughing, sneezing, sore throat, skin ulcers and other signs of infection, as this may be due to low white cell counts.
- Black discolouration of the skin around the injection site.
- A combination of chills or fever, fainting, fast heartbeat, hives, itching, low blood pressure, rash or redness of the face, base of neck, upper body, back and arms, as this may indicate a condition known as Red-Man Syndrome.

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

- Any skin rash other than those mentioned above.
- Fever and/or chills.
- Pain, redness and swelling around the injection site.

Check with your doctor or nurse if any of the following side-effects continue or become bothersome:

- Vomiting, nausea, diarrhoea (runny stomach) and stomach pain.
- Itching.
- Headache.
- Flushing of the upper body.

Treatment with **CIPLA-TEICOPLANIN** may result in infection with organisms not sensitive to it. This may present with thrush (in the mouth or in the genital area) or diarrhoea or any other symptoms related to infection, such as fever, chills, etc. Please report any such symptoms to your doctor as a matter of urgency.

Not all side-effects reported for **CIPLA-TEICOPLANIN** are included in this leaflet. Please tell your doctor or pharmacist of any other undesirable effects you think may be due to receiving **CIPLA-TEICOPLANIN**, especially if not mentioned in this leaflet.

STORING AND DISPOSING OF CIPLA-TEICOPLANIN:

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

CIPLA-TEICOPLANIN vials must be stored at or below 30 °C.

After being mixed with water for injection, the **reconstituted product should be used immediately and any remaining solution must be discarded.**

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

PRESENTATION OF CIPLA-TEICOPLANIN:

CIPLA-TEICOPLANIN 200: Pack of 1 x 10 ml transparent glass vial with grey rubber stopper and red aluminium flip-off seal containing 200 mg teicoplanin.

CIPLA-TEICOPLANIN 400: Pack of 1 x 10 ml transparent glass vial with grey rubber stopper and green aluminium flip-off seal containing 400 mg teicoplanin.

IDENTIFICATION OF CIPLA-TEICOPLANIN:

Lyophilised product:

CIPLA-TEICOPLANIN 200: White to off-white powder/cake.

CIPLA-TEICOPLANIN 400: White to off-white powder/cake.

REGISTRATION NUMBERS:

CIPLA-TEICOPLANIN 200: **43/20.1.1/0610**

CIPLA-TEICOPLANIN 400: **43/20.1.1/0611**

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

CIPLA MEDPRO (PTY) LTD

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Mispel Street

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