**PATIENT INFORMATION LEAFLET**

**CIPLA AZITHROMYCIN 500 INJ**

**SCHEDULING STATUS:** S4

**CIPLA AZITHROMYCIN 500 INJ**, 500 mg powder for solution for infusion.

**Active substances:**

Each CIPLA AZITHROMYCIN 500 INJ vial contains 500 mg of azithromycin (as the dihydrate), providing 100 mg/mL solution following reconstitution.

Sugar free.

**Read all of this leaflet carefully before you are given CIPLA AZITHROMYCIN 500 INJ**

- 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 AZITHROMYCIN 500 INJ is and what it is used for
2. What you need to know before you take CIPLA AZITHROMYCIN 500 INJ
3. How to take CIPLA AZITHROMYCIN 500 INJ
4. Possible side effects
5. How to store CIPLA AZITHROMYCIN 500 INJ

6. Contents of the pack and other information.

## 1. What CIPLA AZITHROMYCIN 500 INJ is and what it is used for

Azithromycin is an antibiotic belonging to the macrolide class of antibiotics.

CIPLA AZITHROMYCIN 500 INJ is indicated for the treatment of pneumonia (lung infection) acquired in the community that is caused by organisms sensitive (susceptible) to azithromycin. It is used in adult patients who require intravenous therapy. Intravenous therapy is therapy given by injection into one's veins. Your doctor will decide whether you qualify for treatment with CIPLA AZITHROMYCIN 500 INJ.

## 2. What you need to know before you take CIPLA AZITHROMYCIN 500 INJ

**CIPLA AZITHROMYCIN 500 INJ should not be administered to you:**

- If you are hypersensitive or allergic to azithromycin, erythromycin or any of the macrolide antibiotics or any component of the formulation.
- If you are using ergot derivatives for the treatment of migraine. Please discuss this with your doctor if you are unsure.
- Suffer from liver disease.
- Are pregnant or breast feeding (see **Pregnancy, breast feeding and fertility**).

CIPLA AZITHROMYCIN 500 INJ should not be given to children.

### Warnings and precautions

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

The presence of other medical conditions may affect the use of CIPLA AZITHROMYCIN 500 INJ. Tell your doctor or pharmacist if any of the following applies to you, as you may require a lower dose or special monitoring:

- Impaired kidney function.
- Impaired liver function.

CIPLA AZITHROMYCIN 500 INJ may cause serious allergic reactions, including severe swelling and severely low blood pressure (shock), which have been fatal in rare instances. You should report any symptoms suggestive of an allergic reaction, such as shortness of breath, swelling of the face or tongue, skin rash, or difficulty breathing, to your doctor as a matter of urgency. Symptoms may sometimes recur, even after CIPLA AZITHROMYCIN 500 INJ has been discontinued. Your doctor may need to monitor you for this.

Treatment with CIPLA AZITHROMYCIN 500 INJ may also cause a condition known as pseudomembranous colitis. Pseudomembranous colitis is an infection of the colon that develops as a complication of treatment with antibiotics. It is characterised by offensive-smelling diarrhoea, fever and stomach pain. Severity can vary from mild to life-threatening. You should report any such symptoms to your doctor as a matter of urgency.

CIPLA AZITHROMYCIN 500 INJ may also cause infection with other organisms not sensitive to it, such as fungal infections presenting with thrush, either oral or vaginal thrush.

Liver damage leading to life-threatening liver failure have been reported with CIPLA AZITHROMYCIN 500 INJ use. If you are presenting with signs and symptoms of liver damage such as rapid loss of energy associated with jaundice, dark urine, bleeding tendency or decreased brain function due to liver damage then you should consult your doctor as liver function tests will need to be performed immediately and your treatment with CIPLA AZITHROMYCIN 500 INJ will need to be stopped.

Treatment with CIPLA AZITHROMYCIN 500 INJ may also cause symptoms of myasthenia gravis (Medical condition leading to skeletal muscle weakness).

**Children**

The safety and efficacy of CIPLA AZITHROMYCIN 500 INJ for the treatment of infections in children has not been established.

**Other medicines and CIPLA AZITHROMYCIN 500 INJ**

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

- Cyclosporin to prevent rejection following an organ transplant.
- Digoxin for the treatment of heart failure or abnormal heart rhythms.

- Warfarin, a medicine to prevent blood clots.
- Alprazolam or triazolam for anxiety or sleeplessness.
- Quinidine for abnormal heart rhythms.
- Sildenafil for erectile dysfunction.
- Simvastatin for high blood cholesterol levels.
- Tacrolimus to prevent rejection following an organ transplant.
- Vinblastine for the treatment of cancer.
- Phenytoin and valproate for the treatment of epilepsy.
- Ergotamine derivatives for treatment of migraine as ergotism may occur and you might experience symptoms such as headache, vomiting and diarrhoea.
- Terfenadine used to treat allergies.

**Pregnancy, breast feeding and fertility**

The safety and efficacy of CIPLA AZITHROMYCIN 500 INJ have not been established in pregnancy and fertility.

CIPLA AZITHROMYCIN 500 INJ passes into breast milk. Because it is not known whether CIPLA AZITHROMYCIN 500 INJ will have an adverse effect on your breast-fed infant, nursing should be discontinued while you are receiving treatment. Diarrhoea, fungus infection of the mucous membrane as well as sensitisation is possible in your nursed infant. It is recommended to discard the breast milk during treatment and up to 2

days after discontinuation of treatment. You may resume breast feeding your infant thereafter.

**Driving and using machines**

There is no evidence to suggest that CIPLA AZITHROMYCIN 500 INJ may have an effect on a patient's ability to drive or operate machines.

It is not always possible to predict to what extent CIPLA AZITHROMYCIN 500 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 AZITHROMYCIN 500 INJ affects them.

**CIPLA AZITHROMYCIN 500 INJ contains**

- Citric acid monohydrate
- 3N Sodium hydroxide.

## 3. How to take CIPLA AZITHROMYCIN 500 INJ

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

CIPLA AZITHROMYCIN 500 INJ will be administered into one of your veins. It will usually be administered in a drip over a period of not less than 60 minutes and will be given intravenously for at least two days. Your doctor will decide the appropriate dosage and how long treatment with CIPLA AZITHROMYCIN 500 INJ will last. Your doctor may

decide to prescribe oral antibiotics after treatment with CIPLA AZITHROMYCIN 500 INJ so that you receive a 7- to 10-day course of antibiotics in total.

If you feel that CIPLA AZITHROMYCIN 500 INJ is too strong or too weak for you, please discuss this with your treating doctor.

You will not be expected to give yourself CIPLA AZITHROMYCIN 500 INJ. It will be given to you by a person who is qualified to do so.

**If you take more CIPLA AZITHROMYCIN 500 INJ than you should**

Typical symptoms of overdosage with CIPLA AZITHROMYCIN 500 INJ include hearing loss, severe nausea, vomiting and diarrhoea.

Since a health care provider will administer CIPLA AZITHROMYCIN 500 INJ, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

**If you forget to take CIPLA AZITHROMYCIN 500 INJ**

Since a health care provider will administer CIPLA AZITHROMYCIN 500 INJ, it is unlikely that the dose will be missed.

## 4. **Possible side effects**

CIPLA AZITHROMYCIN 500 INJ can have side effects.

Not all side effects reported for CIPLA AZITHROMYCIN 500 INJ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLA AZITHROMYCIN 500 INJ, please consult your health care provider for advice.

If any of the following happens, stop taking CIPLA AZITHROMYCIN 500 INJ and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Foul-smelling diarrhoea, fever and stomach pain, as this may indicate pseudomembranous colitis (see **Warnings and precautions**).
- Blood in the stool or black tarry stools accompanied by stomach pain.
- Sore throat, fever and/or chills, ulcers, shortness of breath or difficulty breathing, stomach pain or any other signs of infection, since CIPLA AZITHROMYCIN 500 INJ may cause low white blood cell counts and platelet counts (Blood clotting factor). White blood cells are necessary to fight infections.
- Convulsions or epileptic fits.
- Hearing loss, deafness or ringing in the ears.
- Jaundice (yellow discolouration of the skin or whites of the eyes) accompanied by pain over the liver area, loss of appetite and tiredness, as this may indicate inflammation of the liver.
- Greatly increased or decreased frequency of urination or amount of urine, inability to pass urine, and/or blood in the urine, as this may indicate inflammation of the kidney or kidney failure.
- Blisters on the skin.

- Swelling, difficulty breathing or tightness of the chest, or skin rash, as this may indicate that you are allergic to CIPLA AZITHROMYCIN 500 INJ as well as an allergic reaction or if you are going into anaphylactic shock.
- Fatigue, chest pain

These are all very serious side effects. If you have them, you may have had a serious reaction to CIPLA AZITHROMYCIN 500 INJ. You may need urgent medical attention or hospitalisation:

- Vaginal discharge or thrush.
- Chest pain or palpitations.
- Runny stomach or vomiting.
- Inflammation or pain at the injection or drip site.
- Arthralgia (Joint pain).
- Sensitivity to light.
- Liver damage and liver failure.
- Anorexia.
- Nervousness, aggressive behaviour, agitation, anxiety.
- Abnormal tingling sensation.
- Inflammation of the pancreas.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Headaches, loss of balance or dizziness, excessive sleepiness, and fatigue.

- Loss of appetite, nausea, flatulence, stomach discomfort, dyspepsia, constipation, and taste disturbances, tongue discolouration.
- Visual impairment.
- Hypotension.
- Abnormal blood test results such as decreased white blood cell count and blood bicarbonate and increased aspartate aminotransferase, alanine aminotransferase, blood bilirubin, blood urea, blood creatinine and blood potassium.

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 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 AZITHROMYCIN 500 INJ. Side effects may also be reported directly to Cipla Medpro (Pty) Ltd: drugsafetysa@cipla.com.

## 5. How to store CIPLA AZITHROMYCIN 500 INJ

Store all medicines out of reach of children.

The centre where you receive treatment with CIPLA AZITHROMYCIN 500 INJ will store and dispose of CIPLA AZITHROMYCIN 500 INJ on your behalf.

CIPLA AZITHROMYCIN 500 INJ should be stored at or below 30 °C.

Keep vial in original packaging until use.

The reconstituted solution is stable for 24 hours when stored below 30 °C. Discard any unused portion thereafter.

## 6. Contents of the pack and other information

### What CIPLA AZITHROMYCIN 500 INJ contains

- The active substance is azithromycin 500 mg (as the dihydrate), providing 100 mg/mL solution following reconstitution.
- The other ingredients are citric acid monohydrate and 3N sodium hydroxide.

### What CIPLA AZITHROMYCIN 500 INJ looks like and contents of the pack

CIPLA AZITHROMYCIN 500 INJ is packaged in a single use 10 mL tubular transparent flint glass vial and closed with a bromobutyl grey colour rubber stopper and aluminium flip-off tear-off seal.

CIPLA AZITHROMYCIN 500 INJ is a white to off white powder/cake. The reconstituted solution is clear and colourless, visually free of undissolved matter and essentially free from particles of foreign matter.

### Holder of Certificate of Registration

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