APPROVED PATIENT INFORMATION LEAFLET

Information for the Patient about

CIPLA AZITHROMYCIN 500 TABLETS

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CIPLA AZITHROMYCIN 500 containing azithromycin 500 mg (tablets)

Read all of this leaflet carefully before you start taking CIPLA AZITHROMYCIN 500.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **CIPLA AZITHROMYCIN 500 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 AZITHROMYCIN 500 CONTAINS:

The active substance is azithromycin. Each **CIPLA AZITHROMYCIN 500** tablet contains azithromycin dihydrate equivalent to 500 mg azithromycin.

Other ingredients are croscarmellose sodium, dicalcium phosphate, magnesium stearate, povidone, sodium lauryl sulphate, starch and Opadry white (containing,

Hypromellose 15cP, polyethylene glycol 6000 and titanium dioxide).

WHAT CIPLA AZITHROMYCIN 500 IS USED FOR:

CIPLA AZITHROMYCIN 500 belongs to a group of antibiotics, called macrolides. It is used to treat infections caused by certain bacteria and other micro-organisms.

These include: *Haemophilus influenzae, Moraxella catarrhalis, Chlamydia trachomatis, Neisseria gonorrhoea, Streptococcus pneumoniae and Haemophilus ducreyi.*

Adults:

- Chest (lung), throat and nasal (in the nose) infections (such as bronchitis, tonsillitis, sinusitis and sore throat).
- Skin and soft tissue infections (such as abscess).
- Genital infections due to certain organisms sensitive to **CIPLA AZITHROMYCIN 500**.

Children: ≥ 45 kg

- **CIPLA AZITHROMYCIN 500** tablets are used for sore throat/tonsillitis and ear infections caused by organisms sensitive to **CIPLA AZITHROMYCIN 500** in children over 45 kg. **CIPLA AZITHROMYCIN 500** must not be given to children below 45 kg.

BEFORE YOU TAKE CIPLA AZITHROMYCIN 500:

Do not take CIPLA AZITHROMYCIN 500 if:

- You are allergic to azithromycin, or any of the macrolide antibiotics, such as erythromycin or clarithromycin, or to any of the other ingredients of this formulation.
- You are taking any ergot derivatives, such as ergotamine (a medicine to treat

migraine), since this may lead to serious side effects, such as constriction of the vessels in your hands and feet accompanied by an unpleasant sensation with normal stimulation.

- You have liver problems or dysfunction characterised by lack of energy, dark urine, sudden bleeding and yellowing of skin or eyes.
- It's for the treatment of infected burn wounds.

Take special care with CIPLA AZITHROMYCIN 500:

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

- Kidney problems.
- Use any other medicines, whether or not your doctor has prescribed them for you (please see **"Taking other medicines with CIPLA AZITHROMYCIN 500"**).

CIPLA AZITHROMYCIN 500 may cause serious allergic reactions, including severe swelling and severely low blood pressure (shock). 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** has been discontinued. Your doctor may need to monitor you for this.

Treatment with **CIPLA AZITHROMYCIN 500** 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 (loose stools), fever and stomach pain. Severity can vary from mild to life-threatening. Please report to your doctor immediately if you develop diarrhoea or any of the other symptoms listed here.

CIPLA AZITHROMYCIN 500 is not intended for the use in prevention of bronchiolitis obliterans syndrome, a lung disease that is characterised by a dry cough, shortness of breath, wheezing as well as feeling tired. Please tell your doctor if you are suffering from the symptoms listed above.

CIPLA AZITHROMYCIN 500 may also cause infection with other organisms not sensitive to it, such as fungal infections presenting with thrush, either oral or vaginal thrush. If you develop white spots in the mouth or a vaginal discharge accompanied by itching, please report to your doctor as soon as possible.

Use in pregnancy and breast feeding:

The safety of **CIPLA AZITHROMYCIN 500** in pregnancy and while breast feeding has not been established.

If you are pregnant or breast feeding your baby while taking CIPLA AZITHROMYCIN 500, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

CIPLA AZITHROMYCIN 500 may cause drowsiness or involuntary muscle movement and hence caution must be taken when driving and using machinery.

Taking other medicines with CIPLA AZITHROMYCIN 500:

If you are taking medicines on a regular basis, including complementary or traditional medicines, related use of these medicines with CIPLA AZITHROMYCIN 500 may cause undesirable interactions. Please consult your doctor or pharmacist, or other healthcare professional for advice.

In particular, please inform your doctor if you are taking any of the following medicines:

- Ergot derivatives for the treatment of migraine. You should not take **CIPLA AZITHROMYCIN 500** with such medicines (please see **"Do not take CIPLA AZITHROMYCIN 500 if"**).
- Antacids for indigestion or heart burn. If you are taking antacids, you should take **CIPLA AZITHROMYCIN 500** tablets at least 1 hour before or 2 hours after the antacid.
- Fluconazole used in the treatment of fungal infections as well as Nelfinavir in the treatment of HIV/AIDS as these drugs increase the blood level concentration of azithromycin which may increase the risk of developing serious side effects.
- Alprazolam, midazolam or triazolam for anxiety or sleeplessness as **CIPLA AZITHROMYCIN 500** may increase blood levels of these medicines, which may in turn increase your risk of developing serious side-effects. This is also true for the following medicines:
    - Cyclosporine to suppress your immune system.
    - Alfentanil used in the relieving of pain
    - Omeprazole for the treatment of stomach ulcers.

- Disopyramide or quinidine for abnormal heart rhythms.
- Sildenafil for erectile dysfunction (impotence).
- 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.

- Theophylline for shortness of breath or tightness of the chest, since your doctor may have to perform blood tests to check your blood theophylline levels.
- Digoxin for the treatment of heart failure or abnormal heart rhythms, since you may have to undergo blood tests for monitoring of your blood digoxin levels.
- Warfarin, a medicine to prevent blood clots, since you may have to undergo more regular blood tests to monitor the efficacy of warfarin.
- The following medicines have no reported interaction with **CIPLA AZITHROMYCIN 500:**
    - Atorvastatin for the use of lowering cholesterol
    - Carbamazepine to treat seizures or nerve pain
    - Cetirizine for the treatment of common allergic reactions
    - Didanosins (Dideoxyinosine) used in the treatment of HIV/AIDS
    - Rifabutin to treat bacterial infections
    - Terfenadine used in the treatment of allergic conditions
    - Trimethoprim/sulfamethoxazole used in the treatment of bacterial infections

HOW TO TAKE CIPLA AZITHROMYCIN 500:

Do not share medicines prescribed for you with any other person

Always take CIPLA AZITHROMYCIN 500 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

CIPLA AZITHROMYCIN 500 should be taken orally as a single daily dose with or without food.

Adults:

The total dose is 1,5 g which should be taken as 500 mg daily for 3 days or 500 mg on day 1 and then 250 mg daily on days 2 – 5. For sexually transmitted diseases the dose is 1 g given as a single dose. Your doctor will decide whether you qualify for treatment with **CIPLA AZITHROMYCIN 500** or not.

Use in the elderly:

Normal adult dosage is recommended.

Use in children:

Children over 45 kg – dose as per adults.

This formulation is not suitable for children under 45 kg.

If you take more CIPLA AZITHROMYCIN 500 than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience side-effects such as those listed below. Typical symptoms of overdosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhoea. **In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.**

If you forget to take CIPLA AZITHROMYCIN 500:

Take **CIPLA AZITHROMYCIN 500** as prescribed. If you miss a dose of this medicine, take it as soon as you remember. However, if you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule of one tablet once a day. Do not take a double dose to compensate for the forgotten individual dose.

<u>POSSIBLE SIDE-EFFECTS</u>:

CIPLA AZITHROMYCIN 500 can have side-effects. Not all side-effects reported for CIPLA AZITHROMYCIN 500 are included in this leaflet. Should your general health worsen while taking CIPLA AZITHROMYCIN 500, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **CIPLA AZITHROMYCIN 500** and tell your doctor immediately or go to the casualty department at your nearest hospital:[1]

- Swelling of the hands, feet , ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- Rash or itching,
- Fainting,
- Yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had serious allergic reaction **CIPLA AZITHROMYCIN 500.** You may need medical attention or hospitalisation.

Tell your doctor immediately or go to casualty department at your nearest hospital

if you notice any of the following:

- Loss of hearing (deafness)
- Palpitations (rapid or irregular heart beat), as this may indicate an abnormal heart rhythm.
- Runny stomach (diarrhoea) with or without stomach cramps, fever, blood in the stool and loss of appetite or generally feeling unwell (see **"Take special care with CIPLA AZITHROMYCIN 500"**).
- Blood in the stool.
- Inability to pass urine, blood in the urine, urinating more frequently or less frequently than usual, swelling of the body and generally feeling unwell as this may indicate kidney damage.
- Blisters on the skin or inside the mouth accompanied by fever as this may indicate serious and potentially life-threatening complications from treatment with **CIPLA AZITHROMYCIN 500**.
- Convulsions or epileptic fits.
- Chest pain
- Visual impairment

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

Tell your doctor if you notice any of the following:

- Vaginal discharge with or without itching.
- Fever, chills, coughing, sneezing, sore throat, skin ulcers and other signs of infection as these symptoms may indicate low white cell counts.
- Numbness or pins and needles.

- Ringing in the ears.
- Any skin rash other than those described above.
- Headache, dizziness, feeling as if the world is spinning or moving, excessive sleepiness, and weakness or tiredness.
- Loss of appetite, nausea, stomach pain or cramps, passing winds, vomiting, indigestion, constipation, and taste disturbances.
- Dehydration.
- Abnormal liver function.
- Abnormal kidney function.
- Disturbances in sleep patterns
- Dry mouth
- Loss of weight
- Back,neck or any other muscle pain
- Hot flushes
- Low blood pressure

Please tell your doctor or pharmacist of any other undesirable effects you think may be due to taking **CIPLA AZITHROMYCIN 500**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF CIPLA AZITHROMYCIN 500:

Store at or below 30 °C. Keep the blister in the outer container until required for use.

STORE THIS MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

PRESENTATION OF CIPLA AZITHROMYCIN 500:

CIPLA AZITHROMYCIN 500: Aluminium foil blister strip containing 3 tablets packed in a carton.

IDENTIFICATION OF CIPLA AZITHROMYCIN 500:

CIPLA AZITHROMYCIN 500: White to off-white, film-coated, capsule-shaped, biconvex tablets plain on one side and central break line on the other.

REGISTRATION NUMBER:

42/20.1.1/0506

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

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

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