Patient Information Leaflet Information for

CIPLOXX 250 / 500 TABLETS

SCHEDULING STATUS: S4

CIPLOXX 250 ciprofloxacin 250 mg, tablets.

CIPLOXX 500 ciprofloxacin 250 mg, tablets.

Ciprofloxacin.

Sugar free

Read all of this leaflet carefully before you start taking CIPLOXX:

- 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.
- CIPLOXX 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 is in the leaflet

1. What CIPLOXX is and what it is used for

CIPLOXX is used in adults to treat severe and/or complicated bacterial infection of the lungs, bladder, gut (diarrhoea), bone, or skin and soft tissues where other antimicrobials used for similar infections were considered not to be an appropriate treatment option, have failed, cannot be used or are not tolerated. It is also used to prevent you getting an infection caused by a bacterium called *Neisseria meningitidis*.

2. What you need to know before you take CIPLOXX

Do not take CIPLOXX

- If you are hypersensitive (allergic) to ciprofloxacin or any of the other ingredients of CIPLOXX (listed in **section 6**).
- **If you or your child are younger than 18 years.**
- If you are pregnant or breastfeeding your baby (see **"Pregnancy, breastfeeding and fertility"**).
- If you are receiving treatment with tizanidine, a muscle relaxant.
- If you have kidney function impairment and are taking medicines to lower your blood pressure, including angiotensin-converting enzyme (ACE) inhibitors (such as enalapril, lisinopril, perindopril), or renin-angiotensin blockers (such as losartan, valsartan, irbesartan).
- If you have previously experienced side effects with the use of quinolone / fluoroquinolone antibiotics relating to your joints, muscles, ligaments, nerves, central nervous system (brain), epilepsy or mental health (psychiatric disorder).
- If you were born with or have any condition with abnormal heart rhythm whether related to QT time prolongation or not (seen on ECG, electrical recording of the heart).
- If you are taking other medicines that result in an abnormal heart rate and/or rhythm tracing (ECG) e.g. (prolongation of the “QT time”).
- If you have an enlargement or “bulge” of a large blood vessel (aortic aneurysm) or a

previous episode of aortic dissection (a tear in the aortic wall) or a family history of aortic aneurysm / dissection, or other risk factors or existing predisposing conditions.

- If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis).
- If you are on treatment for high blood pressure with medicines called ACE inhibitors / angiotensin receptor blockers. Ask your doctor if you are unsure.
- If you have mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out).

Warnings and precautions

Take special care with CIPLOXX:

Your doctor may decide to conduct laboratory tests to establish if CIPLOXX will be effective in treating your infection and may also decide to prescribe CIPLOXX together with other medicines, depending on your infection.

Allergic reactions, which may include a skin rash with blister formation, peeling or purple/red inflamed spots on your skin, difficult breathing and swallowing, wheezing, hives, itching, or swelling of the lips, face, tongue or whole body may occur with CIPLOXX, sometimes after the first dose. If you experience any of these symptoms during treatment stop taking CIPLOXX immediately and contact your doctor as these symptoms may be due to an allergic reaction that may become life-threatening (see **“Possible side effects”**).

Tell your doctor if you have previously suffered a tendon disease / disorder related to other quinolone antibiotics. Treatment with CIPLOXX may cause inflammation of a tendon and/or a tear in a tendon (particularly of the Achilles tendon – see **"Possible side effects"**), especially in older people and in those treated concurrently with corticosteroids (e.g. cortisone or prednisone). This can occur within 48 hours after starting treatment or several months

afterwards. If you experience pain, swelling or redness of any tendon, immediately stop taking CIPLOXX and rest the affected limb(s). Report to your doctor promptly while avoiding any form of physical exercise.

Inform your doctor if you have been diagnosed with myasthenia gravis, as worsening of muscle paralysis has been reported with CIPLOXX. This may be severe enough to cause life-threatening breathing difficulties (see **"Do not take CIPLOXX"**).

Avoid exposure to strong sunlight or sun lamps while taking CIPLOXX, since CIPLOXX may increase the sensitivity of your skin to sunlight (see **"Possible side effects"**). Stop taking CIPLOXX and report to your doctor if you develop a skin rash in areas exposed to the sun (e.g. face or hands).

Before you take CIPLOXX, inform your doctor if you have epilepsy, a history of convulsions or seizures, or if you have been diagnosed with arteriosclerosis (build-up of plaques) of the arteries in your brain, or stroke. Convulsions (seizures) have been reported with the use of CIPLOXX, sometimes after the first dose (see **"Possible side effects"**).

Tell your doctor if you have been diagnosed with depression or any psychiatric disease, as you may develop psychiatric reactions even after the first dose of CIPLOXX. In some people such reactions have progressed to suicidal thoughts and self-endangering behaviour or suicide. If you develop these reactions, treatment with CIPLOXX should be stopped.

If you experience numbness and tingling in the feet or hands, sharp or burning pain, extreme sensitivity to touch, lack of coordination and falling, muscle weakness or paralysis, you should stop taking CIPLOXX immediately to avoid developing nerve damage.

CIPLOXX may give rise to abnormal heart rhythms. The use of certain other medicines (such as amiodarone, quinidine, sotalol, erythromycin and certain antidepressants and

antipsychotics, amongst others) may further increase this risk (see **"Other medicines and CIPLOXX"**). You must immediately stop taking CIPLOXX and report to your doctor if you experience fainting spells or palpitations. Please inform your doctor before you start taking CIPLOXX, if you have a personal or family history of heart rhythm disorders, or if you have been diagnosed with heart failure, a heart attack, slow heart rate or low blood levels of potassium or magnesium. Women and the elderly may be more sensitive to these effects of CIPLOXX.

If you have a family history of aortic aneurysm or aortic dissection or other risk factors or existing predisposing conditions (e.g. connective tissue disorders such as Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, high blood pressure or known atherosclerosis) (see **"Do not take CIPLOXX"**).

Tell your doctor if you have been diagnosed with mitral valve or aortic valve regurgitation (when your heart's mitral or aortic valve does not close tightly, causing blood to flow back into the heart instead of pumping out). Your doctor will perform a thorough examination of your heart, including an echocardiogram, since CIPLOXX should not be taken if you have mitral valve or aortic valve regurgitation (see **"Do not take CIPLOXX"**).

CIPLOXX may affect your blood sugar (glucose) levels. It may increase or decrease your blood sugar levels and is more likely to affect people that have been diagnosed with diabetes mellitus and are taking oral antidiabetic medicine(s) or are using insulin, and in the elderly. Very high or low blood glucose levels may result in a coma. If you have been diagnosed with diabetes mellitus, you (in conjunction with your doctor) will have to monitor your blood glucose levels carefully while you are taking CIPLOXX. Report to your doctor if you develop excessive hunger or thirst, frequent urination, blurred vision, fatigue, sweating, shaking or trembling, or if you feel faint or dizzy.

Report to your doctor if you develop stomach cramps, loose stools (diarrhoea), fever, or blood in the stool after taking CIPLOXX, as this may be due to an infection of the large bowel which,

in some instances, may become life-threatening. Your doctor will prescribe appropriate treatment.

It is important that you drink sufficient fluids to ensure that you pass enough urine while taking CIPLOXX to prevent the formation of urinary crystals. You should avoid taking urinary alkalisers, such as citrates and sodium bicarbonate.

Please inform your doctor if you have been diagnosed with impaired kidney function, as you may require a lower dosage of CIPLOXX.

Before you start taking CIPLOXX, tell your doctor if you are taking blood pressure lowering medicines called ACE inhibitors (such as enalapril, lisinopril, perindopril), or renin-angiotensin receptor blockers (such as losartan, valsartan, irbesartan), as taking CIPLOXX with these medicines may cause damage to your kidneys, especially if you have existing kidney problems or are over the age of 65 (see **"Do not take CIPLOXX"**). If your doctor has approved the use of these medicines with CIPLOXX your kidney function will be monitored before and during treatment.

If you experience signs or symptoms of reduced appetite, dark urine, yellowing of the skin or white parts of your eyes, pain over the liver area or itching skin, stop taking CIPLOXX immediately and contact your doctor.

Please inform your doctor if you have been diagnosed with glucose-6-phosphate dehydrogenase deficiency (an inherited disorder). People with glucose-6-phosphate dehydrogenase deficiency are more likely to develop tiredness, pale skin, shortness of breath, or palpitations (due to a reduction in the number of red blood cells) while taking CIPLOXX. Please report any of these symptoms to your doctor as soon as possible.

If you are taking CIPLOXX for a lengthy period, it can lead to overgrowth of non- responsive

organisms. Consult your doctor to ensure appropriate action is taken for secondary infections.

Tell your doctor if you are taking any other medicines, as CIPLOXX may cause higher blood levels of certain medicines, which should be monitored closely by your doctor to prevent overdose (see **"Other medicines and CIPLOXX"**).

Tell your doctor if you are receiving treatment with methotrexate, an immune suppressant, as your dosage of methotrexate may have to be adjusted while you are taking CIPLOXX.

Treatment with CIPLOXX may interfere with laboratory tests used in the diagnosis of certain diseases and cause false negative results.
CIPLOXX may interfere with the interpretation of diagnostic culture tests for tuberculosis.

Report to your doctor if you develop easy bruising, pinpoint red spots on the skin, bleeding from the gums, pale skin, unusual tiredness or weakness, fever and chills, coughing, ulcers that do not heal, or sore throat as these symptoms may be due to abnormal blood cell and platelet counts that may become life-threatening (see **"Possible side effects"**).

If you experience blurred vision or other problems with your eyesight, you should report to your doctor immediately.

If you are currently taking other medicines that can reduce your blood potassium levels.

You should not take fluoroquinolone/ quinolone antibacterial medicines, including CIPLOXX, if you have experienced any serious adverse reaction in the past when taking a quinolone or fluoroquinolone medicines. In this situation, you should inform your doctor as soon as possible.

Children and adolescents

Do not give CIPLOXX to children younger than 18 years.

Other medicines and CIPLOXX

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Please inform your doctor if you are taking any of the following medicines, as you may require a reduction in dose or special precautions:

- Medicines to treat abnormal heart rhythms, e.g. quinidine, amiodarone, sotalol (see **"Warnings and precautions"**).
- Erythromycin (an antibiotic), medicines for the treatment of psychosis (e.g. risperidone, quetiapine, olanzapine), or antidepressants (e.g. agomelatine, amitriptyline, clomipramine), since these medicines may increase your risk of developing abnormal heart rhythms (see **"Warnings and precautions"**).
- Antacids or sucralfate (for stomach ulcers), multivitamins or products containing magnesium, calcium, aluminium or iron, sevelamer or lanthanum carbonate (called phosphate binders), and medicines containing magnesium, calcium, or aluminium (e.g. didanosine or other antiretroviral medicines used in the treatment of HIV). These medicines may reduce the absorption of CIPLOXX. CIPLOXX should, therefore, be taken 1 to 2 hours before, or at least 4 hours after any of these medicines (see **"How to take CIPLOXX"**).
- Non-steroidal anti-inflammatory medicines (NSAIDs), e.g. fenbufen, diclofenac or ibuprofen, for pain and fever. Please discuss this with your doctor, as use of CIPLOXX with any of these medicines may increase the risk of developing convulsions / seizures (see **"Warnings and precautions"**).
- Probenecid (for gout).
- Metoclopramide (for nausea and vomiting or migraines).
- Omeprazole, for stomach ulcers.
- Tizanidine, a muscle relaxant (see **"Do not take CIPLOXX"**).

- Zolpidem, for insomnia (sleeplessness).
- Methotrexate or ciclosporin (immune suppressants). Your doctor will need to monitor your blood levels of methotrexate or ciclosporin and may need to adjust your dose.
- Theophylline (for chronic bronchitis or emphysema), caffeine, pentoxifylline (for pain associated with your veins), or phenytoin (for epilepsy). Your doctor will need to monitor your blood levels of these medicines, and you may require a dose adjustment.
- Warfarin (a blood thinner) and other blood thinners. Concurrent use of CIPLOXX may increase your chance of bleeding. Your doctor will need to monitor your prothrombin time / INR (international normalised ratio) when you are taking CIPLOXX.
- Glibenclamide for diabetes mellitus. It is recommended that you monitor your blood sugar levels carefully while taking CIPLOXX, as CIPLOXX may cause low blood sugar levels.
- Duloxetine (an antidepressant), ropinirole (for Parkinson's disease), lidocaine (lignocaine) for local anaesthesia, clozapine (for treatment of psychological disorders, i.e. schizophrenia), or sildenafil (for erectile dysfunction or impotence). Your doctor will need to monitor your blood levels of these medicines, and you may require a dose adjustment.
- Enalapril, lisinopril, perindopril (ACE inhibitors), or losartan, valsartan, or irbesartan (renin-angiotensin receptor blockers), for high blood pressure. Combining these medicines with CIPLOXX may cause damage to your kidneys (see **"Do not take CIPLOXX"**).
- If you are on treatment with ACE inhibitors / angiotensin receptor blockers used to control your blood pressure. Ask your doctor if you are not sure.

CIPLOXX with food, drink and alcohol

CIPLOXX should be swallowed whole with a full glass of water and may be taken with or

without meals.

CIPLOXX should not be taken with dairy products (e.g. yoghurt, milk) or with mineral fortified drinks (e.g. calcium fortified orange juice), as it will reduce the absorption of CIPLOXX from your stomach (see **"How to take CIPLOXX"**).

Taking CIPLOXX with alcohol may cause impairment of your ability to drive or operate machinery (see **"Driving and using machinery"**).

Pregnancy, breastfeeding and fertility

You should not use CIPLOXX during pregnancy or when breastfeeding your baby.

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 healthcare professional for advice before taking CIPLOXX.

Driving and using machines

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

3. How to take CIPLOXX

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

Always take CIPLOXX exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

CIPLOXX should be swallowed whole with a full glass of water and may be taken with or without meals (see **"CIPLOXX with food, drink and alcohol"**).

CIPLOXX should not be taken with dairy products (e.g. yoghurt, milk) or with mineral fortified drinks (e.g. calcium fortified orange juice), as it will reduce the absorption of CIPLOXX from

your stomach (see **"CIPLOXX with food, drink and alcohol"**).

The usual dose is one CIPLOXX tablet every twelve hours (twice daily) for 5 to 10 days. Depending on your diagnosis, your doctor may decide to treat you for longer or shorter periods of time. It is important that you take CIPLOXX for as long as your doctor prescribes it (i.e. finish the course of treatment).

Your doctor will adjust your dosage if you have impaired kidney function.

If you have the impression that the effect of CIPLOXX is too strong or too weak, tell your doctor or pharmacist.

If you take more CIPLOXX 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 any of the side effects listed below. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take CIPLOXX

Always take CIPLOXX as prescribed. It is important that you complete the full course of treatment. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CIPLOXX

Not applicable.

4. Possible side effects

CIPLOXX can have side effects.

Not all side effects reported for CIPLOXX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLOXX, please consult your doctor, pharmacist or other healthcare provider for advice.

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

- Allergic reactions, which may include a skin rash, fever, difficult breathing, wheezing, hives, itching, or swelling of the face, lips, tongue, throat and airways (breathing tubes), difficult breathing, blueness of the skin, low blood pressure, heart failure and can result in death.
- Difficult breathing, swelling of the throat.
- Yellowing of the skin and eyes, also called jaundice.
- Any skin rash with blister formation (which may be life-threatening), or purple / red, inflamed spots on your skin.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CIPLOXX. 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:

- Those that occur frequently:
    - Bruising of the skin, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, shortness of breath upon exertion, unusual tiredness or weakness, fever and chills, as these symptoms may be due to abnormal blood cell and platelet counts.
    - Rashes, hives, itching.

- Those that occur less frequently:
    - Fungal infections and fungal infections resistant to usual treatment.

- Stomach pain or cramps, vomiting, bloody stools, fever or watery diarrhoea (loose stools), as this may be due to an infection of the gut which, in some instances, may become life-threatening.
- Excessive hunger or thirst, frequent urination, blurred vision, fatigue, weakness, sweating, shaking or trembling, or if you feel faint or dizzy (especially if you have been diagnosed with diabetes mellitus), since this may be due to high or low blood sugar levels and may result in coma.
- Seeing or hearing things that are not real, psychotic reactions or depression (which may include self-endangering behaviour such as thinking about suicide or attempting suicide).
- Pins and needles.
- Unsteady gait, epileptic seizures / convulsions, tremor (trembling), disturbed coordination.
- Fainting spells, headache, nausea and vomiting, blurred vision, which may be caused by increased pressure in the brain.
- Abnormal or a reduced sense of touch or sensation.
- Involuntary movements, extreme sensitivity to touch, muscle spasms, twitching.
- Impaired sense of smell, loss of the sense of smell (usually reversible when stopping treatment).
- Fast, pounding heartbeat.
- Flushing / redness of the skin, fainting spells.
- Low blood pressure, causing you to feel dizzy or light-headed especially upon standing up.
- Swelling of the feet, hands or face, pain, redness, and tenderness of a vein.
- Yellow discolouration of the skin or whites of the eyes (especially in people with liver damage) accompanied by loss of appetite, nausea, pain over the liver area and fever, with or without loss of consciousness, as this may

indicate inflammation of the liver or pancreas, which may be life-threatening.

- Skin rash, or redness of the skin in areas exposed to the sun.
- Pain, swelling or redness of the joints, muscle pain, stiffness or cramping.
- Pain, swelling or redness over a tendon (e.g. the Achilles tendon), torn tendon.
- Muscle weakness (especially in patients diagnosed with myasthenia gravis).
- Urinary stones, cloudy, dark or discoloured urine, reduced frequency of urination, difficulty passing urine, pain over the bladder or kidneys and swelling of the feet, legs or hands.
- Development of severe and persistent diarrhoea can be related to inflammation of the bowel (colitis) linked to antibiotic use.

- Those that occur with unknown frequency:
  - Numbness and tingling in the feet or hands.
  - Fast or irregular heartbeat, dizziness, light-headedness, shortness of breath, chest pain, fainting spells with or without exercise, or coughing when lying down, or prolonged QT interval on the electrocardiogram.
  - Inflamed blisters on the skin (acute generalised exanthematous pustulosis) with or without fever, rash, facial swelling, enlarged lymph glands and kidney or liver problems (medicine reaction with eosinophilia and systemic symptoms syndrome).
  - Difficulty sleeping, fluid retention or excessive sweating relating to a condition called Syndrome of inappropriate secretion of antidiuretic hormone (SIADH).

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

Tell your doctor if you notice any of the following:

- Those that occur frequently:
    - Sleeplessness, agitation, confusion.
    - Dizziness, headache, taste loss, impaired sense of taste.
    - Nausea, loose stools, vomiting, indigestion, stomach pain, loss of appetite, flatulence (gas).
    - Joint pain.
    - General feeling of weakness, tiredness.

- Those that occur less frequently:
    - Anxiety, abnormal dreams (nightmares), irritability, restlessness, disorientation, sleep disorders.
    - Migraine.
    - Blurred vision, double vision, disturbance in colour vision or eye movement.
    - Ringing in the ears, temporary deafness / impairment of hearing (especially at high frequencies), feeling that you or your environment is moving or spinning.
    - Thrush / vaginal yeast infection, yeast infection of the mouth, throat or gut.
    - Stomach pain, constipation, sores in the mouth, difficulty swallowing.
    - Back and chest pain, pain in the extremities, worsening gout.
    - Pain, fever, sweating, tiredness, feeling unwell.
    - Sudden severe pain in your chest, abdomen (tummy) or back.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform

(who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CIPLOXX.

5. How to store CIPLOXX

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep blister strips in outer carton until required for use.

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 (e.g. toilets).

6. Contents of the pack and other information

What CIPLOXX contains

The active ingredient in CIPLOXX is ciprofloxacin.

Each CIPLOXX 250 tablet contains ciprofloxacin hydrochloride equivalent to 250 mg of ciprofloxacin.

Each CIPLOXX 500 tablet contains ciprofloxacin hydrochloride equivalent to 500 mg of ciprofloxacin.

The other ingredients are colloidal silica, croscarmellose sodium, Hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, purified talc and titanium dioxide.

What CIPLOXX looks like and contents of the pack

CIPLOXX 250: White, film-coated, circular, biconvex tablet, plain on one face and with a deep score and ‘CP 250' debossed on the other face.

Colourless, transparent PVC, aluminium blister packs of 6 and 10 tablets packed in a carton.

CIPLOXX 500: White, film-coated, capsule-shaped, biconvex tablet, plain on one side with a break line and ‘CP 500’ debossed on the face.

Colourless transparent PVC, aluminium blister packs of 10 tablets packed in a carton.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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CIPLOXX 250

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Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.