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SCHEDULING STATUS

S4

CIPROBAY® IV 100 mg, 200 mg, 400 mg Solution for Infusion
Ciprofloxacin
Sugar free

Read all of this leaflet carefully before you are given CIPROBAY.

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

1. What CIPROBAY is and what it is used for

CIPROBAY is an antibiotic belonging to the fluoroquinolone family. The active substance is ciprofloxacin. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

CIPROBAY is used in adults to treat severe and/or complicated bacterial infections 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 use CIPROBAY

CIPROBAY should not be administered to you:

- If you are hypersensitive (allergic) to ciprofloxacin or any of the other ingredients of CIPROBAY (listed in section 6).
- 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 are pregnant or breastfeeding your baby
- if you are taking medicines which contain tizanidine to treat spasticity (tight or rigid muscles) because this may cause side effects such as low blood pressure and sleepiness.
- 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 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 have other risk factors or existing predisposing conditions.
- If you have a damaged mitral and/or aortic heart valve which cannot close properly.
- If you have myasthenia gravis (abnormal muscle fatigue leading to weakness and, in serious cases, paralysis).
- **if you or your child are younger than 18 years.**
- If you are on treatment for high blood pressure with medicines called ACE inhibitors/angiotensin-receptor blockers. Ask your doctor if you are unsure.

Warnings and precautions
Talk to your doctor or health care provider before CIPROBAY is administered for the first time if you:

- have ever had kidney problems as your doctor may need to adjust the dose.
- suffer from epilepsy or other neurological conditions, such as fits (see *CIPROBAY should not be administered to you*).
- have a history of tendon problems during previous treatment with antibiotics such as CIPROBAY (see *CIPROBAY should not be administered to you*).
- have myasthenia gravis (a type of muscle weakness) because taking CIPROBAY may worsen your symptoms of the disease (see *CIPROBAY should not be administered to you*).
- have heart problems. Caution should be taken when using CIPROBAY, if you are born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have salt imbalance in the blood (especially low level of potassium or magnesium in the blood), have a very slow heart rate (called 'bradycardia'), have a weak heart (heart failure), have a history of heart attack (myocardial infarction), you are female or elderly or you are taking other medicines that result in abnormal ECG changes (see *CIPROBAY should not be administered to you* and O*ther medicines and CIPROBAY*).
- suffer from depression or other mental health problems (see *CIPROBAY should not be administered to you*).
- have a damaged mitral and/or aortic heart valve which cannot close properly.
- have diabetes. Fluoroquinolone antibiotics, including CIPROBAY may cause disturbances in your blood sugar level, especially if you are elderly and treated with oral medicines or insulin to lower your blood sugar. Your doctor may wish to monitor your blood sugar during treatment with CIPROBAY.
- are currently taking other medicines that can reduce your blood potassium levels.
- have a family history of aortic aneurysm or aortic dissection or other risk factors or 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 *CIPROBAY should not be administered to you*).

Tell your doctor immediately, if any of the following occurs while taking CIPROBAY. Your doctor will decide whether treatment with CIPROBAY needs to be stopped.

- Severe, sudden allergic reaction (an anaphylactic reaction/shock, angioedema). Even with the first dose, there is a risk that you may experience a severe allergic reaction with the following symptoms: tightness in the chest, feeling dizzy, sick or faint, or experiencing dizziness when standing up. If this happens, stop taking CIPROBAY and contact your doctor immediately.
- Inflammation and tearing of tendons may occur even within the first 48 hours of treatment or up to several months after stopping CIPROBAY therapy. The risk of inflammation and tearing of tendons may be increased if you are elderly, during strenuous physical activity, if you are currently being treated with corticosteroids, if you have impaired kidney function or have received solid organ transplants. At the first sign of any pain or inflammation stop taking CIPROBAY, rest the painful area and consult your doctor immediately. Avoid any unnecessary exercise, as this might increase the risk of your tendon tearing. The recovery process for your tendons, muscles and joints may take weeks or months and full recovery to

what it was before treatment with CIPROBAY may not occur (see *CIPROBAY should not be administered to you*).

- If you suffer from epilepsy or other neurological conditions such as cerebral ischaemia or stroke, you may experience side effects associated with the central nervous system. If this happens, stop taking CIPROBAY and contact your doctor immediately (see *CIPROBAY should not be administered to you*).
- You may experience mental health problems the first time you receive CIPROBAY. If you suffer from depression or psychosis, your symptoms may become worse under treatment with CIPROBAY. Depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking CIPROBAY and contact your doctor immediately (see *CIPROBAY should not be administered to you*).
- You may experience symptoms of nerve damage (neuropathy) such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, stop taking CIPROBAY and contact your doctor immediately. The recovery process for your nerve condition may take weeks or months and full recovery to what it was before your treatment with CIPROBAY may not occur (see *CIPROBAY should not be administered to you*).
- CIPROBAY may cause liver damage. If you notice any symptoms such as loss of appetite, jaundice (yellowing of the skin), dark urine, itching, or tenderness of the stomach, stop taking CIPROBAY and contact your doctor immediately.

If you suffer from diarrhoea while receiving CIPROBAY tell your doctor immediately as this may become life-threatening. Do not take medicines to stop it without checking with your doctor or pharmacist first.

Your skin may become more sensitive to sunlight or ultraviolet (UV) light when taking CIPROBAY. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds.

Tell the doctor or laboratory staff that you are taking CIPROBAY if you have to provide a blood or urine sample.

CIPROBAY may interfere with the interpretation of diagnostic culture tests for tuberculosis.

Children and adolescents

Do not give CIPROBAY to children and adolescents younger than 18 years due to the increased risk of damage to the cartilage of weight bearing joints.

Other medicines and CIPROBAY

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

If you are taking any of the following medicines, please consult your healthcare professional:

- medicines that can affect your heart rhythm: medicines that belong to the group of Class IA and III anti-dysrhythmics, tricyclic antidepressants, some antibiotics (that belong to the group of macrolides), some antipsychotics (used for schizophrenia)
- a class of anti-coagulants (to prevent blood clots) which inhibits Vitamin K (e.g. warfarin)
- methotrexate (for certain types of cancer, psoriasis or rheumatoid arthritis)
- theophylline (for breathing problems)
- clozapine (antipsychotic - used for schizophrenia)
- ropinirole (for Parkinson’s disease)
- metoclopramide (for nausea and vomiting)
- omeprazole (for heartburn, indigestion or ulcers in the stomach or intestines)
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplants)

- duloxetine (for depression, diabetic nerve damage or incontinence)
- lignocaine (for heart conditions or anaesthetic use)
- sildenafil (e.g. for impotence or high blood pressure)
- nonsteroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen (for pain, fever or inflammation)
- medicines containing caffeine
- pentoxifylline (for circulation disorders)
- phenytoin (for epilepsy)
- ACE inhibitors/angiotensin blockers to control your blood pressure. Ask your doctor if you are not sure.
- Agomelatine (for depression)
- Zolpidem (for sleep disorders)

Pregnancy and breastfeeding

You should not receive CIPROBAY during pregnancy or when breastfeeding your baby. It can harm your baby. Tell your doctor if you are pregnant or if you are planning to get pregnant before receiving CIPROBAY.
If you are receiving CIPROBAY you should not breastfeed your baby. Ciprofloxacin is excreted in your breast milk and may harm your baby.

If you are pregnant or breastfeeding your baby while taking this medicine please consult your doctor, pharmacist, or other health care professional for advice.

Driving and using machinery

CIPROBAY may affect your ability to drive and operate machinery. Therefore, make sure you know how you react to CIPROBAY before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

CIPROBAY contains sodium

This product contains sodium. Talk to your doctor if you are on a controlled sodium diet.

3. How to use CIPROBAY

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

You will not be expected to give yourself CIPROBAY. It will be given by a healthcare professional who is qualified to do so.

Your doctor will explain to you exactly how much CIPROBAY you will be given as well as how often and for how long. This will depend on the type and severity of infection you have.

Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

Your doctor or nurse will give you each dose of the solution for infusion through a needle, into a vein and then into your bloodstream. The infusion duration is 60 minutes.

Your skin may show a reaction at the site where the needle is inserted. This will usually clear up once the infusion is finished.

Elderly

Elderly patients should receive a dose as low as possible depending on the severity of their illness and how well their kidneys are working.

If you received more CIPROBAY than you should

In the event of overdosage your doctor will take the necessary corrective action.

4. POSSIBLE SIDE EFFECTS

CIPROBAY can have side effects.

Not all side effects reported for CIPROBAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CIPROBAY, please consult your doctor, pharmacist or other health care professional for advice.

If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.
CIPROBAY should be stopped and your doctor be informed at once if you have a serious side effect such as:

- angioedema (rapid swelling of the skin and mucous membranes of the face, lips, tongue, or throat with difficulty to breathe);
- anaphylactic reaction/shock which is a severe sudden allergic reaction and is rapid in onset. Symptoms of anaphylactic reaction include dizziness (feeling dizzy, sick or faint or experiencing dizziness when standing up), tightness in the chest, loss of consciousness, difficulty in breathing, swelling of the face, lips, tongue, throat and airways (breathing tubes), blueness of the skin, low blood pressure, heart failure, and can result in death.
- sudden severe pain in your chest, abdomen (tummy), or back;
- severe dizziness, fainting, fast or pounding heartbeats;
- sudden pain, snapping or popping sound, bruising, swelling, tenderness, stiffness, or loss of movement in any of your muscles, ligaments or joints;
- diarrhoea that is watery or bloody;
- confusion, hallucinations, depression, unusual thoughts or behaviour;
- seizure (convulsions);
- pale or yellowed skin, dark coloured urine, fever, weakness;
- urinating less than usual or not at all;
- easy bruising or bleeding;
- numbness, tingling, burning sensation, weakness, or unusual pain anywhere in your body;
- the first sign of any skin rash, no matter how mild; or
- severe skin reaction - fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

Frequent side effects include:

- Nausea, diarrhoea, vomiting, stomach and abdominal pains, indigestion/heartburn, flatulence (gas)
- Injection site reaction
- Yeast/mould (mycotic) superinfections
- High concentration of eosinophils (type of white blood cells)
- Loss of appetite (anorexia)
- Hyperactivity/agitation
- Headache, dizziness, sleep problems (insomnia or nightmares), taste disorders
- Increase in transaminases or increased bilirubin (increased amounts of certain substances in the blood)

- Rash, itching (pruritus), or hives (urticaria)
- Joint pain
- Poor kidney function
- Unspecific pain, feeling unwell, or fever
- Increase in blood alkaline phosphatase (a certain substance in the blood)

Less frequent side effects include:

- Antibiotic-related colitis (inflammation of the bowel linked to antibiotic use)
- Leukopenia, anaemia, neutropenia, leucocytosis (changes in blood count), thrombocytopenia or thrombocytaemia (increased or decreased amounts of blood platelets), haemolytic anaemia (a special type of anaemia due to red blood destruction), agranulocytosis (a drop in a type of white blood cells), or pancytopenia (a dangerous drop in the number of red and white blood cells and platelets) which may be life-threatening; or bone marrow depression, which may also be life-threatening
- Allergic reaction, allergic oedema (swelling) or angioedema (rapid swelling of the skin and mucous membranes), anaphylactic reaction (allergic reaction), anaphylactic shock (severe allergic reaction which may be life-threatening); serum sickness-like reaction (an allergic reaction)
- Blood glucose disorders: low blood glucose (hypoglycaemia), high blood glucose- (hyperglycaemia) or other changes in blood glucose
- Confusion and disorientation, anxiety reactions, abnormal (strange) dreams, depression which may lead to self-harm, such as thoughts of suicide and attempted or completed suicide, or hallucinations, psychotic reactions (mental disturbances) that may lead to self-harm such as suicidal ideations/thoughts and attempted or completed suicide
- Paraesthesia ('pins and needles'), dysesthesia (disturbed sensation) or hypoesthesia (reduced sensation), tremors, seizures including status epilepticus (prolonged or repeated fits or seizures without any recovery between attacks), vertigo, migraine, disturbed coordination, smell disorders, hyperesthesia (increased sensitivity to stimuli), or intracranial hypertension including pseudotumour cerebri (pressure on the brain)
- Visual disturbances (eyesight problems), visual colour distortions
- Tinnitus (ringing in the ears), loss of hearing, impaired hearing
- Tachycardia (rapid heartbeat)
- Vasodilatation (expansion of blood vessels), hypotension (low blood pressure), or syncope (fainting), inflammation of the walls of the blood vessels (vasculitis)
- Dyspnoea (shortness of breath) including asthmatic condition
- Pancreatitis (inflammation of the pancreas)
- Hepatic impairment (liver disorders), jaundice, or non-infective hepatitis, liver necrosis very rarely progressing to life-threatening hepatic failure
- Photosensitivity reactions (sensitivity to light), or blistering (blistering of the skin), petechiae (small, pin-point bleeding under the skin), erythema multiforme, erythema nodosum (various skin eruptions, blisters, peeling or rashes); Stevens-Johnson syndrome or toxic epidermal necrolysis which may be life-threatening (severe allergic skin reactions)
- Myalgia (muscle pain), arthritis (inflammation of the joints), or increased muscle tone and cramping, muscular weakness, tendinitis, tendon rupture predominantly Achilles tendon (especially of the large tendon at the back of the ankle), or exacerbation of symptoms of myasthenia gravis (worsening of the symptoms of myasthenia gravis, a muscle weakness)
- Renal failure (kidney failure), haematuria (blood in the urine), crystalluria (crystals in the urine) or tubulointerstitial nephritis (a type of urinary tract inflammation)
- Sweating (hyperhidrosis) (excessive sweating), gait disturbance (unsteady walk)
- Abnormal prothrombin (a clotting factor) level or increased amylase (increased levels of the enzyme amylase)

In isolated instances, some serious adverse drug reactions may be long-lasting (> 30 days) and disabling; such as tendinitis, tendon rupture, musculoskeletal disorders, and other reactions affecting the nervous system including psychiatric disorders and disturbance of senses.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

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 pharmacist. 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 CIPROBAY.

5. How to store CIPROBAY

Store all medicines out of the reach and sight of children. Do not store in bathrooms.
Do not store above 30 °C. Protect from light, avoid excessive heat. Do not refrigerate or freeze.
At cool storage temperatures precipitation may occur, which will re-dissolve at room temperature.
Do not remove from the original packaging until administered.
Do not use after the expiry date stated on the label.
Return unused or expired medicines to your pharmacist for safe disposal.

6. Contents of the pack and other information

What CIPROBAY contains

The active substance is ciprofloxacin.
CIPROBAY IV contains 2,0 mg ciprofloxacin per mL in 0,9 % sodium chloride solution.

CIPROBAY IV solution for infusion comes in 3 strengths: 100 mg, 200 mg and 400 mg.
100 mg/50 mL: Each glass bottle with 50 mL infusion solution contains 100 mg ciprofloxacin.
200 mg/100 mL: Each glass bottle with 100 mL infusion solution contains 200 mg ciprofloxacin.
400 mg/200 mL: Each glass bottle with 200 mL infusion solution contains 400 mg ciprofloxacin.

The other ingredients are lactic acid, sodium chloride, hydrochloric acid and water for injection.

What CIPROBAY looks like and content of the pack

Nearly colourless to slightly yellowish solution in a glass bottle.
CIPROBAY IV is available in different volumes: 50 mL, 100 mL and 200 mL glass infusion bottles.

Holder of Certificate of Registration

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
Isando
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