SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CIPROBAY® XR 500 500 mg modified release tablet
Ciprofloxacin 500 mg
Sugar free

CIPROBAY® XR 1000 1 000 mg modified release tablet
Ciprofloxacin 1 000 mg
Sugar free

Read all of this leaflet carefully before you start taking CIPROBAY XR

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

CIPROBAY XR 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 XR 500 is used to treat uncomplicated bacterial bladder infections and CIPROBAY XR 1000 is used to treat an acute uncomplicated kidney infection in adults where treatment with other appropriate antimicrobials approved for similar infections and to which the bacteria are sensitive have failed, cannot be used, or are not tolerated.
CIPROBAY XR 1000 is used to treat severe and/or complicated bacterial infections of the bladder and gut (diarrhoea) in adults where other antimicrobials used for similar infections are considered not to be an appropriate treatment option, have failed, cannot be used, or are not tolerated.

2. What you need to know before you take CIPROBAY XR

Do not take CIPROBAY XR:

- If you are hypersensitive (allergic) to ciprofloxacin or any of the other ingredients CIPROBAY XR (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 a damaged mitral and/or aortic valve which cannot close properly.
- If you have a salt imbalance in the blood (especially low levels of potassium or magnesium in the blood).
- 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 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 before taking CIPROBAY XR the first time if you:

- have ever had kidney problems because your treatment may need to be adjusted;
- suffer from epilepsy or other neurological conditions such as fits;
- have a history of tendon problems during previous treatment with antibiotics such as CIPROBAY XR (see Do not take Ciprobay XR);
- have myasthenia gravis (a type of muscle weakness) because taking CIPROBAY XR may worsen the symptoms of your disease (see Do not take CIPROBAY XR);
- have heart problems. Caution should be taken when using CIPROBAY XR, if you are born with or have family history of prolonged QT interval (seen on ECG, electrical recording of the heart), have a 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 Other medicines and CIPROBAY XR).
- if you have a damaged mitral and/or aortic valve which cannot close properly.
- suffer from depression or other mental health problems (see Do not take CIPROBAY XR);
- have diabetes. CIPROBAY XR 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 XR.
- 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 Do not take CIPROBAY XR).

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

- **Severe, sudden allergic reaction** (an anaphylactic reaction/shock). Even with the first dose, there is a chance 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 XR and contact your doctor

immediately.

- Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after completion of CIPROBAY XR therapy. The risk of inflammation and rupture 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 XR, rest the painful area and consult your doctor immediately. Avoid any unnecessary exercise, as this might increase the risk of a tendon rupture. The recovery process for your tendons, muscles and joints may take weeks or months and full recovery to your pre-treatment condition may not occur (see Do not take CIPROBAY XR).
- If you suffer from **epilepsy** or other **neurological conditions** such as reduced cerebral flow or stroke, you may experience side effects associated with the central nervous system. If this happens, stop taking CIPROBAY XR and contact your doctor immediately (see Do not take CIPROBAY XR).
- You may experience **mental health problems** the first time you take CIPROBAY XR. If you suffer from depression or psychosis, your symptoms may become worse under treatment with CIPROBAY XR. Depression or psychosis can progress to thoughts of suicide, suicide attempts, or completed suicide. If this happens, stop taking CIPROBAY XR and contact your doctor immediately (see Do not take CIPROBAY XR).
- You may experience symptoms of **neuropathy (nerve damage)** such as pain, burning, tingling, numbness and/or weakness in your limbs. If this happens, stop taking CIPROBAY XR and contact your doctor immediately. The recovery process for your nerve condition may take weeks or months and full recovery to your pre-treatment condition may not occur (see Do not take CIPROBAY XR).
- CIPROBAY XR 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 XR and contact your doctor immediately.
- **Severe ongoing (persistent) diarrhoea** may develop while you are taking CIPROBAY XR, or even several weeks after you have stopped taking it. If it happens, stop taking CIPROBAY XR immediately, as this can be life-threatening. Do not take medicines that stop or slow down bowel movements and contact your doctor.
- Tell the doctor or laboratory staff that you are taking CIPROBAY XR if you have to provide a blood or urine sample.
- CIPROBAY XR may cause a reduction in the number of white blood cells and your **resistance to infection may be decreased**. If you experience an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems you should see your doctor immediately. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis). It is important to inform your doctor about the CIPROBAY XR that you are using.
- Your skin becomes more **sensitive** to sunlight or ultraviolet (UV) light when taking CIPROBAY XR. Avoid exposure to strong sunlight, or artificial UV light such as sunbeds. Stop taking CIPROBAY XR if sunburn-like reactions occur.

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

Children and adolescents

Do not give CIPROBAY XR 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 XR

Always tell your health care professional 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 (an 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 transplantation)
- duloxetine (for depression, diabetic nerve damage or incontinence)
- lignocaine (for heart conditions or anaesthetic use)
- sildenafil (e.g. for impotence or high blood pressure)
- NSAIDs such as ibuprofen (for pain, fever or inflammation)
- pentoxifylline (for circulation disorders)
- medicines containing caffeine
- phenytoin (for epilepsy)
- agomelatine (for depression)
- zolpidem (for sleep disorders)
- ACE inhibitors/angiotensin blockers to control your blood pressure. Ask your doctor if you are not sure.
- medicines which reduce the uptake of CIPROBAY XR. If these medicines are essential, take CIPROBAY XR about two hours before or no sooner than four hours after them. They include:
  - sucralfate (used to treat heartburn, indigestion or ulcers in the stomach or intestines)
  - antacids (used to treat indigestion)
  - highly buffered medicines such as didanosine (used to treat HIV)
  - a polymeric phosphate binder such as sevelamer or lanthanum carbonate (to lower the level of phosphates in patients with kidney problems)
  - medicines or dietary supplements containing calcium, magnesium, aluminium or iron

Taking CIPROBAY XR with dairy products (e.g. milk, yoghurt) should be avoided because the absorption of CIPROBAY XR can be reduced.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

CIPROBAY XR with food and drink

- CIPROBAY XR tablets are to be swallowed whole with a small amount of fluid. CIPROBAY XR tablets must not be crushed, divided or chewed for intake.
- CIPROBAY XR tablets can be taken independently of mealtimes. CIPROBAY XR tablets should not be taken at the same time with dairy products or with mineral-fortified drinks alone (e.g. milk, yoghurt, calcium-fortified orange juice).

Pregnancy and Breastfeeding

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

- You should not use CIPROBAY XR during pregnancy. Tell your doctor, pharmacist or any other health care professional if you are pregnant or planning to get pregnant (see Do not take CIPROBAY XR).
- You should not use CIPROBAY XR when breastfeeding your baby because ciprofloxacin is excreted in breast milk and may be harmful to your baby (see Do not take CIPROBAY XR).

If you are pregnant or breastfeeding your baby while taking CIPROBAY XR please consult your doctor, pharmacist, or other healthcare professional for advice.

Driving and using machinery

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

3. How to take CIPROBAY XR

Do not share medicines prescribed for you with any other person.
Always take CIPROBAY XR exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.
Tell your doctor if you suffer from kidney problems because your dose may need to be adjusted.

The usual dose for an uncomplicated bladder infection (urinary tract infections): 500 mg once daily for 3 days.
The usual dose for a complicated bladder or kidney infection (urinary tract infection): 1 000 mg once daily for 7-14 days.
The usual dose for bacterial diarrhoea: 1 000 mg once daily for up to 7 days.
The duration of treatment depends on the type and severity of infection that you have. The doctor will decide on the duration of treatment.

CIPROBAY XR tablet should not be crushed or divided for intake and should be swallowed whole with plenty of liquid with or without meals.
You can take the CIPROBAY XR film-coated tablets at mealtimes or in between meals. Do not take CIPROBAY XR film-coated tablets with dairy products such as milk or yoghurt or with fortified fruit-juice (e.g. calcium-fortified orange-juice) because these can affect how well your body absorbs CIPROBAY XR. If you are also taking medicines or mineral supplements containing calcium, magnesium, or aluminium, such as certain types of antacids used to treat indigestion, you should take your dose of CIPROBAY XR either 1–2 hours before or at least 4 hours after taking your other medicine.
Remember to drink plenty of fluids while you are taking CIPROBAY XR.

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 take more CIPROBAY XR than you should

If you take more than the prescribed dose, get medical help immediately. If possible, take your tablets or the box with you to show the doctor.
Kidney damage can occur when too many tablets have been taken. If you have taken more tablets, you may feel lethargic, may also experience generalized swelling, shortness of breath, decreased muscle

function among other symptoms of kidney damage. Please consult your doctor immediately if you have taken more tablets than you should.

If you forget to take a dose of CIPROBAY XR

If you forget to take your tablet and it is:

- 8 hours or more until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
- Less than 8 hours until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.

If you stop taking CIPROBAY XR

It is important that you finish the course of treatment even if you begin to feel better. If you stop taking CIPROBAY XR too soon, your infection may not be completely cured, and the symptoms of infection may return or get worse or the bacteria may become resistant to the medicine.

4. Possible side effects

CIPROBAY XR can have side effects.
Not all side effects reported for CIPROBAY XR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPROBAY XR, 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.

Stop using CIPROBAY XR and call your doctor at once if you have a serious side effect such as:

- angioedema (rapid swelling of the skin and mucous membranes including face, lips, tongue and 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.
- 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;
- sudden severe pain in your chest, abdomen (tummy) or back;
- 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, 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)

- 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 which may affect blood clotting), haemolytic anaemia (a special type of anaemia due to red blood cell 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 potentially leading to self-injurious behaviour, such as thoughts of suicide and attempted or completed suicide, or hallucinations, psychotic reactions (mental disturbances) potentially culminating (leading) in self-injurious behaviour, 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 which may progress 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 side effects 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 XR.

5. How to store CIPROBAY XR

Store all medicines out of the sight and reach of children.
Store the medication at or below 25 ºC in a dry place.
Do not store in bathrooms.
Do not use after the expiry date stated on the label.
Return all unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CIPROBAY XR contains

The active substance is ciprofloxacin (as ciprofloxacin hydrated and hydrochloride).

CIPROBAY XR 500
Each 500 mg tablet contains 500 mg ciprofloxacin (as ciprofloxacin hydrated and hydrochloride).

CIPROBAY XR 1000
Each 1 000 mg tablet contains 1 000 mg ciprofloxacin (as ciprofloxacin hydrated and hydrochloride).

The other ingredients are crospovidone, hypromellose, magnesium stearate, polyethylene glycol, silica colloidal (anhydrous), succinic acid and titanium dioxide.

What CIPROBAY XR looks like and contents of the pack

CIPROBAY XR 500 modified-release film-coated tablets

Nearly white to slightly yellowish coated oblong tablet with C 500 QD marked on the upper side and BAYER on the lower side.
Blister pack containing 3 tablets or a plastic bottle containing 3 tablets.

CIPROBAY XR 1000 modified-release film-coated tablets
Nearly white to slightly yellowish coated oblong tablet with C 1000 QD marked on the upper side and BAYER on the lower side.
Blister pack containing 7 tablets or a plastic bottle containing 7 tablets.

Holder of Certificate of Registration

Bayer (Pty) Ltd
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27 Wrench Road, Isando, 1609

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