PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: \$4

BIOTECH CIPROFLOXACIN 250 Film coated tablets BIOTECH CIPROFLOXACIN 500 Film coated tablets BIOTECH CIPROFLOXACIN 750 Film coated tablets

Ciprofloxacin hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking BIOTECH CIPROFLOXACIN.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIOTECH CIPROFLOXACIN 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 BIOTECH CIPROFLOXACIN is and what it is used for
- 2. What you need to know before you take BIOTECH CIPROFLOXACIN
- 3. How to take BIOTECH CIPROFLOXACIN
- 4. Possible side effects
- 5. How to store BIOTECH CIPROFLOXACIN
- 6. Contents of the pack and other information

1. What BIOTECH CIPROFLOXACIN is and what it is used for

BIOTECH CIPROFLOXACIN belongs to a group of antibiotics called the fluoroquinolones. It kills the bacteria by

inhibiting certain bacterial enzymes responsible for the replication of the bacteria.

BIOTECH CIPROFLOXACIN 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 BIOTECH CIPROFLOXACIN

Do not take BIOTECH CIPROFLOXACIN tablets:

- if you are hypersensitive (allergic) to ciprofloxacin or any of the other ingredients of BIOTECH CIPROFLOXACIN (listed in section 6).
- if you are pregnant or breastfeeding your baby
- BIOTECH CIPROFLOXACIN should not be used in children under the age of 18 years and in growing adolescents
- 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 mitral valve and or/ aortic valve regurgitation (a heart condition where the mitral and/ or aortic valve

does not close properly)

- 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 in patients with moderate to severe renal impairment and in the elderly
- if you are taking tizanidine (for muscle spasticity in multiple sclerosis).

Warnings and precautions

Take special care with BIOTECH CIPROFLOXACIN:

- if you have a history of seizures or convulsive disorders
- if you are using medicines that will cause your urine to become alkaline or if you experience crystals in your
 urine which causes kidney pain or discomfort when passing urine. You should be well hydrated and avoid
 excessive alkalinity of the urine when taking BIOTECH CIPROFLOXACIN
- if you are currently taking other medicines that can reduce your blood potassium levels
- if you have heart problems. Caution should be taken when using BIOTECH CIPROFLOXACIN, if you were 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 rhythm (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 section 2: Other medicines and BIOTECH CIPROFLOXACIN).
- if you have been diagnosed with leaking heart valves (heart valve regurgitation).
- 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 BIOTECH CIPROFLOXACIN)
- if you are taking ACE inhibitors/renin-angiotensin receptor blockers (treating high blood pressure) and

especially if your kidney function is impaired. The concomitant use of BIOTECH CIPROFLOXACIN and the abovementioned medicine can cause acute kidney injury. Your doctor should monitor your kidney function before and during treatment (see Do Not Use BIOTECH CIPROFLOXACIN)

- if you have an infection of the urinary tract, your doctor will prescribe BIOTECH CIPROFLOXACIN based on the laboratory results
- if your doctor is treating you for Travellers' diarrhoea, your doctor must take the information on the resistance of the pathogens of the countries you visited into account
- if you are being treated for an infection of your bones or joints, your doctor will prescribe another antibiotic as combination to BIOTECH CIPROFLOXACIN depending on laboratory results
- you should not take fluoroquinolone/ quinolone antibacterial medicines, including BIOTECH
 CIPROFLOXACIN, if you have experienced any serious adverse reaction in the past when taking a quinolone
 or fluoroquinolone. In this situation, you should inform your doctor as soon as possible
- if you experience painful swelling of your tendons, particularly the Achilles (heel) tendon, you should avoid any physical exercise and your doctor should be consulted. BIOTECH CIPROFLOXACIN may cause these side effects. Inflammation and ruptures of tendons may occur even within the first 48 hours of treatment or up to several months after discontinuation of BIOTECH CIPROFLOXACIN therapy. Avoid any unnecessary exercise as this might increase the risk of tendon rupture
- if you experience symptoms of neuropathy such as pain, burning, tingling, numbness and/ or weakness. If this
 happens stop taking BIOTECH CIPROFLOXACIN and contact your doctor immediately (see Do Not Take
 BIOTECH CIPROFLOXACIN)
- if you feel sudden, severe pain in your abdomen, chest or back, immediately go to an emergency room
- if your eyesight becomes impaired or if your eyes seem to be otherwise affected, consult an eye specialist immediately
- avoid direct exposure to excessive sunlight and UV-light
- if you notice an atypical, widespread rash, which may occur in conjunction with high body temperature and

enlarged lymph nodes, you should seek medical attention immediately

- if you experience any psychiatric reactions such as depression or psychosis or thoughts about suicide or selfharm, after taking BIOTECH CIPROFLOXACIN, consult with your doctor immediately (see Do Not Take BIOTECH CIPROFLOXACIN)
- if you are a diabetic patient receiving concurrent treatment with an oral medicine to lower your blood glucose
 or insulin. Disturbances in blood glucose including too high and too low blood glucose levels have been
 reported. Your doctor will carefully monitor your blood glucose level
- if you experience severe and persistent diarrhoea during or after your treatment, you should consult your doctor as soon as possible
- BIOTECH CIPROFLOXACIN 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 BIOTECH CIPROFLOXACIN and contact your doctor immediately
- if you or a member of your family is known to have a deficiency in glucose-6-phosphate dehydrogenase (G6PD)

 (disease of the red blood cells based on a hereditary enzyme deficiency) because taking BIOTECH

 CIPROFLOXACIN may lead to a destruction of red blood cells causing anaemia. Signs of anaemia are a feeling

 of weakness and in more severe cases, breathlessness and pale skin
- tell your doctor if you are chronically using theophylline (usually used for asthma) clozapine, olanzapine, ropinirole, tizanidine, duloxetine or agomelatine
- tell your doctor if you have impaired liver or kidney function. Your doctor will have to adjust your dosage
- if you have myasthenia gravis (a type of muscle weakness) because symptoms can be exacerbated (see Do not take BIOTECH CIPROFLOXACIN)
- if you are epileptic or suffer from other neurological conditions, you might experience side effects associated
 with the central nervous system. If this happens, stop taking BIOTECH CIPROFLOXACIN immediately, and
 contact your doctor
- BIOTECH CIPROFLOXACIN may cause a reduction in the number of white blood cells and your resistance to

infection may be decreased. If you experience symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as a sore throat/ pharynx/ mouth or urinary problems, inform your doctor immediately

- BIOTECH CIPROFLOXACIN may interfere with the interpretation of diagnostic culture tests for tuberculosis
- if you are taking blood or urinary samples, inform the doctor or laboratory staff.

Children and adolescents

Do not give BIOTECH CIPROFLOXACIN to children younger than 18 years because of the risk of developing arthropathy. BIOTECH CIPROFLOXACIN is unlikely to be safe.

Other medicines and BIOTECH CIPROFLOXACIN

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking:

- 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
- ACE inhibitors/angiotensin receptor blockers (for high blood pressure) it may cause acute kidney injury
 (AKI) especially if you are elderly, your kidneys aren't working properly, you are taking water tablets, NSAIDs
 or dehydrated (see Do not use BIOTECH CIPROFLOXACIN)
- anti-dysrhythmics: medicines that can alter your heart rhythm (e.g., quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, dofetilide, ibutilide), tricyclic antidepressants, some antimicrobials (that belong to the group of macrolides), some antipsychotics
- probenecid (for gout)
- metoclopramide (for nausea and vomiting)

- Do not use BIOTECH CIPROFLOXACIN and a medicine called tizanidine together, it may cause low blood pressure and sleepiness (see Do not use BIOTECH CIPROFLOXACIN)
- Concomitant use of BIOTECH CIPROFLOXACIN and methotrexate (used in certain types of cancer, psoriasis, rheumatoid arthritis) may result in increased blood levels of methotrexate and increased risk of methotrexate toxicity. Concomitant use is not recommended
- Concurrent use of BIOTECH CIPROFLOXACIN with theophylline (a medicine used for asthma) may cause
 in an increase in the theophylline plasma concentrations. As a result, you may experience more theophyllinerelated side effects
- If you use phenytoin for epilepsy, concurrent use with BIOTECH CIPROFLOXACIN will result in lower phenytoin blood levels plasma concentrations. Your doctor must monitor your phenytoin dosage after you stopped BIOTECH CIPROFLOXACIN treatment
- ciclosporin (for skin conditions, rheumatoid arthritis and in organ transplantation)
- medicines used to stop your blood from clotting such as vitamin K antagonists (e.g., warfarin, acenocoumarol, phenprocoumon or fluindione) or other oral anti-coagulants (to thin the blood)
- ropinirole (for Parkinson's disease)
- clozapine (antipsychotics)
- BIOTECH CIPROFLOXACIN may increase the blood levels of zolpidem (for sleep disorders) therefore concurrent use is not recommended
- Concurrent use of non-steroidal anti-inflammatory drugs such as fenbufen may increase the risk of seizures.
 The simultaneous administration of BIOTECH CIPROFLOXACIN and warfarin may increase the change of bleeding
- If you are a diabetic and use glibenclamide, concurrent treatment with BIOTECH CIPROFLOXACIN may cause hypoglycaemia (low blood sugar).

BIOTECH CIPROFLOXACIN may increase the levels of the following medicines in your blood:

- pentoxifylline (for circulatory disorders), caffeine
- duloxetine (for depression, diabetic nerve damage or incontinence)
- lidocaine (for heart conditions or anaesthetic use)
- sildenafil (e.g., for erectile dysfunction)
- agomelatine (for depression)

Some medicines reduce the effect of BIOTECH CIPROFLOXACIN:

- Medicines containing sucralfate or iron and antacids reduce the absorption of BIOTECH CIPROFLOXACIN,
 causing it to be less effective. If you have to use these products, use it 2 hours after or 6 hours before you take
 BIOTECH CIPROFLOXACIN
- omeprazole

BIOTECH CIPROFLOXACIN tablets with food or drink

You may take BIOTECH CIPROFLOXACIN with meals or on an empty stomach. However, do NOT take BIOTECH CIPROFLOXACIN with dairy products or calcium-fortified juices alone. Large amounts of dairy products particularly milk or yoghurt may slow down BIOTECH CIPROFLOXACIN uptake, therefore ciprofloxacin as contained in BIOTECH CIPROFLOXACIN should be taken 1 to 2 hours before or at least 4 hours after these products.

Pregnancy and breastfeeding

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 provider for advice before taking BIOTECH CIPROFLOXACIN.

BIOTECH CIPROFLOXACIN should not be used if you are pregnant or breastfeeding.

Driving and using machines

BIOTECH CIPROFLOXACIN may impair your ability to drive or to operate machinery, especially if you used alcohol concurrently. BIOTECH CIPROFLOXACIN may make you feel less alert. Some neurological adverse events can occur.

It is not always possible to predict to what extent BIOTECH CIPROFLOXACIN may interfere with the daily activities of a patient. You should ensure that you do not engage in driving a vehicle or operating machinery until you are aware of the measure to which BIOTECH CIPROFLOXACIN affects you.

3. How to take BIOTECH CIPROFLOXACIN

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

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

Your doctor will decide on the duration of treatment. Your doctor will explain to you exactly how much BIOTECH CIPROFLOXACIN you will have to take as well as how often and for how long. This will depend on the type and severity of infection you have. The usual treatment period is 5 to 10 days.

For severe and complicated infections more prolonged therapy may be required.

The dose range is 250 - 750 mg twice daily. The tablet must be swallowed whole with plenty of liquid and may be taken with or without meals.

• Severe and/or complicated infections of the lower respiratory tract:

750 mg twice daily

• Severe and/or complicated infectious diarrhoea:

500 mg twice daily

• Severe and/or complicated infection of the urinary tract:

500 mg twice daily

• Severe and/or complicated infections of the skin and bone infections:

750 mg twice daily

For the prophylaxis of invasive infections of Neisseria meningitides, take one single dose of 500 mg.

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 BIOTECH CIPROFLOXACIN than you should

In the event of overdosage, consult your doctor of pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BIOTECH CIPROFLOXACIN

Do not take a double dose to make up to the forgotten individual doses. Continue to take the next tablet at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

4. Possible side effects

BIOTECH CIPROFLOXACIN can have side effects.

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

If any of the following happens, stop taking BIOTECH CIPROFLOXACIN and tell your doctor immediately or go

to the casualty department of your nearest hospital:

- seizures (fits)
- allergic reactions with symptoms such as 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
- muscle weakness, pain, swelling or inflammation of the tendons (ligaments), or if you have difficulty walking,
 as it may be a sign of rupture of a tendon, particularly affecting the Achilles tendon (the large tendon at the back of the ankle)
- if you develop a serious skin rash in the form of blistering and peeling of the skin, if you develop blisters or ulcers in the mouth, throat, nose, eyes and other mucous membranes or sensitivity to sunlight
- flu-like symptoms, followed by a painful red or purplish rash that spreads, blisters on your skin, mouth, nose or genitals, or red, painful, watery eyes, signs of the potentially fatal Stevens-Johnson syndrome or toxic epidermal necrolysis
- unusual feelings of pain, burning, tingling, numbness and general muscle weakness (neuropathy), especially in your arms or legs
- sudden severe pain in your chest, abdomen (tummy) or back
- the development of severe and persistent diarrhoea can be related to inflammation of the bowel (colitis) linked to antibiotic use
- yellowing of the skin and eyes, also called jaundice (cholestatic icterus)
- high or low blood sugar, especially in diabetic patients
- if you have any suicidal thoughts or thoughts about self-harm
- a drug reaction that causes rash, fever, inflammation of internal organs, haematologic abnormalities (including
 increased white blood cells (eosinophilia) and liver enzymes) and systemic illness (DRESS Drug Reaction with
 Eosinophilia and Systemic Symptoms, AGEP Acute Generalised Exanthematous Pustulosis)
- kidney failure, blood or crystals in the urine.

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

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Biotech Ciprofloxacin 250, 500, 750 (A40/20.1.1/0368/69/70) Each film coated tablet contains ciprofloxacin hydrochloride equivalent to 250 mg, 500 mg or 750 mg ciprofloxacin, respectively

CIPROFLOXACIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

• nausea, diarrhoea

Less frequent side effects:

- fungal superinfections, antibiotic-associated colitis is an inflammation of the large intestine
- a high concentration of eosinophils, a type of white blood cell
- changes to the blood count (leukopenia, leukocytosis, neutropenia, anaemia), increased or decreased amounts of a blood clotting factor (thrombocytes)
- reduction in red blood cells due to extensive destruction of these cells (haemolytic anaemia), a dangerous drop in a type of white blood cells (agranulocytosis), a drop in the number of red and white blood cells and platelets (pancytopenia), which may be fatal; and bone marrow depression, which may also be fatal
- allergic reaction, swelling (oedema), or rapid swelling of the skin and mucous membranes (angio-oedema)
- decreased appetite
- headache, dizziness, sleep disorders
- pins and needles, unusual sensitivity to stimuli of the senses, decreased skin sensitivity, tremors
- migraine, disturbed coordination, unsteady walk (gait disturbance), disorder of sense of smell (olfactory disorders), pressure on the brain (intracranial pressure and pseudotumor cerebri), vertigo
- psychiatric problems such as a sense that things are not there (hallucinations), restlessness, tiredness, feel anxious
 or nervous, confusion, depression, trouble sleeping, abnormal dreams
- double vision, colour disturbances
- ringing sound in the ears, loss of hearing, impaired hearing
- increased heart rate (tachycardia)

- widening of blood vessel (vasodilation), low blood pressure, inflammation of the wall of the blood vessels (vasculitis), fainting, flushing of the skin
- shortness of breath (dyspnoea) including asthmatic symptoms
- pancreatitis (swelling and inflammation of the pancreas) causing sever upper abdominal burning pain that
 spreads to your back, nausea and vomiting
- vomiting, bloating, indigestion, abdominal pain, flatulence
- increased number of certain substances in the blood (transaminase and/ or bilirubin)
- liver impairment
- death of liver cells (liver necrosis) very rarely leading to life-threatening liver failure
- hives, sensitivity to light, small pin-point bleeding under the skin (petechiae); various skin eruptions or rashes
- tender red nodules or lumps that are usually seen on both shins
- general feeling of weakness and myalgia (muscle pain in back, chest, body), muscle cramps, inflammation of the tendons
- worsening of the symptoms of myasthenia gravis
- urinary tract inflammation, kidney failure
- feeling unwell (asthenia), or fever
- sweating (hyperhidrosis)
- increased levels of the enzyme amylase, blood alkaline phosphatase

Frequency unknown side effects:

- difficulty sleeping, fluid retention or excessive sweating relating to a condition called Syndrome of inappropriate secretion of antidiuretic hormone (SIADH)
- mood state characterised by persistent disinhibition and elevation (euphoria) and overactivity
- damage to the nerves located outside of the brain and spinal cord (peripheral nerves), often causes weakness, numbness and pain, usually in the hands and feet (peripheral neuropathy and polyneuropathy)

- heart rhythm abnormalities, irregular heartbeat, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)
- influence on blood clotting (in patients treated with Vitamin K antagonists)

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 "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 BIOTECH CIPROFLOXACIN.

5. How to store BIOTECH CIPROFLOXACIN

Store all medicines out of reach of children.

Store in a cool dry place at or below 25 °C.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What BIOTECH CIPROFLOXACIN contains

The active substance is ciprofloxacin hydrochloride, 250 mg, 500 mg or 750 mg per film coated tablet, respectively. The other ingredients are colloidal silicon dioxide, crospovidone, magnesium stearate, microcrystalline cellulose, Opadry Y-1-7000 white (consisting of hypromellose 2910, polyethylene glycol 400, titanium dioxide), polyethylene glycol 4000 and pregelatinised starch.

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What BIOTECH CIPROFLOXACIN looks like and contents of the pack

BIOTECH CIPROFLOXACIN 250: White coloured, biconvex, circular film coated tablet, embossed NJB on one

side and 250 on other side.

BIOTECH CIPROFLOXACIN 500: White coloured, biconvex, capsule shaped film coated tablet, embossed NJB

on one side and 500 on other side.

BIOTECH CIPROFLOXACIN 750: White coloured, biconvex, capsule shaped film coated tablet, embossed NJB

on one side and 750 on other side.

BIOTECH CIPROFLOXACIN 250 and 500 are available in either of the following presentations:

- White HDPE containers containing 50 or 100 tablets

- Transparent PVC and silver aluminium blister strips containing 10 tablets per strip and 1 strip per outer carton.

BIOTECH CIPROFLOXACIN 750 is packed in white HDPE containers containing 50 or 100 tablets.

Holder of Certificate of Registration

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BIOTECH CIPROFLOXACIN 250: A40/20.1.1/0368

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BIOTECH CIPROFLOXACIN 500: A40/20.1.1/0369

BIOTECH CIPROFLOXACIN 750: A40/20.1.1/0370