

# BIOTECH CIPROFLOXACIN

PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS:

S4

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 taking 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 Traveller's 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 self-harm, 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, risperidone, 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
- probencid (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 theophylline-related 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 chance 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 meningitidis*, 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 over dosage, consult your doctor or 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 Exanthematosus 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 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 severe upper abdominal burning pain that spreads to your back, nausea and vomiting  
• vomiting, bloating, indigestion, abdominal pain, flatulence  
• increased amount 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

# BIOTECH CIPROFLOXACIN

PASIËNTINLIGTINGSPAMFLET

## SKEDULERINGSTATUS:

S4

BIOTECH CIPROFLOXACIN 250 Filmbedekte tablette  
BIOTECH CIPROFLOXACIN 500 Filmbedekte tablette  
BIOTECH CIPROFLOXACIN 750 Filmbedekte tablette  
Siprofloxasienhidrochloried

Suiker-vry

## Lees die hele pamflet noukeurig deur voordat jy begin om BIOTECH CIPROFLOXACIN te neem.

- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy enige verdere vrae het, vra asseblief jou dokter, apoteker, verpleegster of ander gesondheidsorgverskaffer.
- BIOTECH CIPROFLOXACIN is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander persone deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

## Wat is in hierdie pamflet

- Wat BIOTECH CIPROFLOXACIN is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy BIOTECH CIPROFLOXACIN neem
- Hoe om BIOTECH CIPROFLOXACIN te neem
- Moontlike newe-effekte
- Hoe om BIOTECH CIPROFLOXACIN te bewaar
- Inhoud van die pak en ander inligting

## 1. Wat BIOTECH CIPROFLOXACIN is en waarvoor dit gebruik word

BIOTECH CIPROFLOXACIN behoort aan 'n groep van antibiotika wat die fluorokinolone genoem word. Dit maak bakterieë dood deur sekere bakteriële ensieme te inhibeer wat verantwoordelik is vir die replikasie van die bakterieë. BIOTECH CIPROFLOXACIN word gebruik in volwassenes om ernstige en/ of gekompliseerde bakteriële infeksie van die longe, blaas, ingewande (diarree), been, of vel en sagte weefsel waar ander antimikrobiële middels wat gebruik word vir soortgelyke infeksies oorweeg is en besluit dat dit nie 'n toepaslike behandelingsopsie is nie, misluk het, kan nie gebruik word nie of nie verdra nie. Dit word ook gebruik vir die voorkoming van infeksies veroorsaak deur 'n bakterie genaamd *Neisseria meningitidis*.

## 2. Wat jy moet weet voordat jy BIOTECH CIPROFLOXACIN neem

### Moenie BIOTECH CIPROFLOXACIN tablete neem nie:

- Indien jy hipersensitief (allergies) is vir siprofloxasien of enige van die ander bestandele van BIOTECH CIPROFLOXACIN (geleys in afdeling 6).
- Indien jy swanger is of jou baby borsvoed
- BIOTECH CIPROFLOXACIN moet nie gebruik word in kinders jonger as 18 jaar oud of in groeiende adolesente nie
- indien jy voorheen newe-effekte ervaar het met kinoloon/ fluorokinoloon antibiotika wat verband hou met jou gewrigte, spiere, ligamente, senueweens, sentrale senueweestelsel (brein), epilepsie of geestestoestand (psigiatrise versturing)
- indien jy gebore is met/of 'n toestand het van abnormalle hartritmte wat verband hou met QT-tydverlenging al dan nie (gesien op EKG, elektriese opname van die hart)
- indien jy ander medisyne neem wat 'n abnormalle hartklop en/ of ritmesporing (EKG) tot gevolg het, bv. (verlenging van die QT-tyd")
- indien jy 'n vergroting of "bulit" van 'n groot bloedvat het (aorta-aneurisme) of 'n vorige episode van aorta-disseksie ('n skeur in die aorta-wand) of 'n familiegeskeidenis van aorta-aneurisme/ disseksie of ander risikofaktore of bestaande predisponerende toestande)
- indien jy mitralisklep en/ of aortaklep regurgitasie het ('n harttoestand waar die mitrale en/ of aortaklep nie behoorlik toemaak nie)
- indien jy myasthenia gravis het (abnormalle spiermoegheid wat lei tot swakheid en in ernstige gevalle, verlamming)
- indien jy op behandeling is vir hoë bloeddruk met medisyne genaamd ACE-inhibeerders/ angiotensienreceptor-blokkers in pasiënte met matige tot ernstige nierinkorting en in die bejaardes
- indien jy tisanidien neem (vir spierspasitesiteit in veulvuldige sklerose).

## Waarskuwings en voorsorgmaatreëls

### Neem spesiale sorg met BIOTECH CIPROFLOXACIN:

- indien jy 'n geskeidenis het van aanvalle (stuiprekings) of konvulsieve versturings
- indien jy medisyne gebruik wat sal veroorsaak dat jou urene alkalies word of as jy kristalle in jou urene opmerk wat nierpyn van ongemak veroorsaak wanneer jy urineer. Jy moet goed gehidreer wees en oormatige alkaliniteit van die urene verminder wanneer jy BIOTECH CIPROFLOXACIN neem
- indien jy huidiglik ander medisyne neem wat jou bloedkaliumvlakte kan verlaag
- indien jy hartprobleme het. Wees versigtig wanneer jy BIOTECH CIPROFLOXACIN neem, as jy gebore is met/of familiegeskeidenis van verlengde QT-interval het (gesien op EKG, elektriese opname van die hart), soutwanbalans in die bloed het (veral lae vlakke van kalium of magnesium in die bloed), 'n baie stadije hartritmte het (genoem 'bradikardie'), 'n swak hart het (hartversaking), 'n geskeidenis van hartaanval het (miokardiale infarksie), jy vroulik is of bejaard, of jy neem ander medisyne wat lei tot abnormalle EKG-veranderinge (sien afdeling 2: Ander medisyne en BIOTECH CIPROFLOXACIN).
- Indien jy gediagnoseer is met lekkende hartklep (hartklep regurgitasie).
- Indien jy 'n familiegeskeidenis het van aorta-aneurisme of aortadisseksie of ander risikofaktore of bestaande predisponerende toestande (bv. bindweefselafwykings soos Marfan-sindroom, Vaskuläre Ehlers-Danlos-sindroom, Takayasu-arteritis, reuse-sel-arteritis, Behcet se siekte, hoë bloeddruk of bekende aterosklerose (sien Moenie BIOTECH CIPROFLOXACIN neem nie)
- indien jy ACE-remmers/ renin-angiotensien-receptorblokkers neem (wat hoë bloeddruk behandel) en veral as jou nierfunksieaangetas is. Die gelykydigheid gebruik van BIOTECH CIPROFLOXACIN en bogenoemde medisyne kan akute nierbesering veroorsaak. Jou dokter moet jou nierfunksiemonitor voor en tydens behandeling (sien Moenie BIOTECH CIPROFLOXACIN gebruik nie)
- indien jy 'n infeksie van die urineweg het sal jou dokter BIOTECH CIPROFLOXACIN voorskryf gebaseer op die laboratoriumresultate
- indien jou dokter jou behandel vir Reisigers se diarree, jou dokter moet die inligting oor die weerstand van die patogene van die lande wat jy besoek het in ag neem
- indien jy vir 'n infeksie van jou bene of gewrigte behandel word, sal jou dokter 'n ander antibiotika in kombinasie met BIOTECH CIPROFLOXACIN voorskryf, afhangende van laboratoriumresultate
- jin moenie fluorokinolon/ kinoloon antibioticale medisyne, insluitend BIOTECH CIPROFLOXACIN, neem as jy in die verlede enige ernstige nadelige reaksie ervaar het wanneer jy 'n kinoloon of fluorokinolon geneem het nie. In hierdie situasie moet jy jou dokter so gou as moontlik in kennis stel
- indien jy 'n pylnlike swelling van jou senings, veral die Achilles (hak) sening ervaar, moet jy enige fisiële oefening vermey en jy moet jou dokter raadpleeg. BIOTECH CIPROFLOXACIN mag hierdie newe-effekte veroorsaak. Inflammasse en skeure van senings mag voorkom, veral binne die eerste 48 uur van behandeling of vir etlike maande nadat jy opgehou het om BIOTECH CIPROFLOXACIN terapie te neem. Vermey enige onnodige oefening omdat dit die risiko van sening-skeur kan verhoog
- indien jy simptome van neuropatië ervaar soos pyn, brandende gevoel, tinteling, gevoelloosheid en/ of swakheid. Indien dit gebeur, hou op om BIOTECH CIPROFLOXACIN te neem en kontak jou dokter onmiddelik (sien Moenie BIOTECH CIPROFLOXACIN neem nie)
- indien jy skielike, erge pyn in jou maag, bors of rug ervaar, gaan onmiddelik na die noodgevalle-afdeling
- indien jou sig versteur word of as jou oë enigsins geaffekteer word, raadpleeg 'n oogspesialis onmiddelik
- vermy direkte blootstelling aan oormatige sonlig en UV lig
- as jy 'n atipiese, wydverspreide uitslag opmerk wat kan voorkom tesame met hoë liggaamstemperatuur en vergrote limfknope moet jy dadelik mediese hulp soek.
- indien jy enige psigiatrise reaksies soos depressie of psigose of gedagtes oor selfmoord of self-skade het nadat jy BIOTECH CIPROFLOXACIN geneem het, raadpleeg jou dokter onmiddelik (sien Moenie BIOTECH CIPROFLOXACIN neem nie)
- indien jy 'n diabetiese pasiënt is wat gelykydig behandel word met 'n orale medisyne ontvang om jou bloedglukose of insuline te verlaag. Sleters in bloedglukose, insluitende die hoë en lae bloedglukosevlakte is aangemeld. Jou dokter sal jou bloedglukosevlakte noukeurig monitor
- indien jy erg en aanhoudende diarree ervaar gedurende en na jou behandeling moet jy jou dokter raadpleeg so gou as moontlik
- BIOTECH CIPROFLOXACIN kan leverbeskadiging veroorsaak: Indien jy kennis neem van enige simptome soos verlies van aptyt, geelsug (vergeling van die vel), donker uriene, jeuk of teerheid van die maag, hou op om BIOTECH CIPROFLOXACIN te neem en kontak onmiddelik jou dokter
- Indien jy 'n familielid bekend is om 'n tekort aan glukose-6-fosfaat dehydrogenase (G6PD) (siekte van die rooibloedselles gebaseer op 'n oorerlike ensimtekort te hê) omdat die neem van BIOTECH CIPROFLOXACIN mag lei tot 'n vernietiging van rooibloedselles wat bloedarmoede veroorsaak. Tekens van bloedarmoede is 'n swak gevoel en in meer ernstige gevalle ameloosheid en bleek vel
- vertel jou dokter indien jy chronies teofilien (gebruik vir asma), closapien, olansapien, ropinirool, tisanidien, duloksetien of agomelatonien neem
- vertel jou dokter indien jy verswakte lewer of nierfunksië het. Jou dokter sal jou dosis wil aanpas
- indien jy myasthenia gravis het ('n type spierswakheid) omdat simptome kan vererger (sien Moenie BIOTECH CIPROFLOXACIN neem nie)
- indien jy epilepties is of aan ander neurologiese toestande ly, kan jy newe-effekte ervaar wat met die sentrale senueweestelsel verband hou. As dit gebeur, hou dadelik op om BIOTECH CIPROFLOXACIN te neem en kontak jou dokter
- BIOTECH CIPROFLOXACIN kan 'n vermindering in die aantal witbloedselles veroorsaak en jou weerstand teen infeksie kan verlaag word. As jy simptome soos koers en ernstige agteruitgang van jou algemene toestand ervaar, of koers met plaaslike infeksie simptome soos 'n seer keel/ farinks/ mond of urinäre probleme, lig jou dokter dadelik in
- BIOTECH CIPROFLOXACIN kan inmeng met die interpretasie van diagnostiese kultuurtoets vir tuberkulose
- Indien jy bloed of urinäre monsters neem, lig die dokter of laboratoriumpersoneel in.

## Kinders en adolescentes

Moenie BIOTECH CIPROFLOXACIN aan kinders jonger as 18 jarige ouderdom gee nie, as gevolg van die risiko om artropatie te ontwikkel. BIOTECH CIPROFLOXACIN is onwaarskynlik om veilig te wees.

## Ander medisyne en BIOTECH CIPROFLOXACIN

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem.

(Dit sluit alle komplementêre of tradisionele medisyne in.)

## Vertel jou dokter indien jy die volgende neem:

- As jy op behandeling is met ACE-remmers/ angiotensien-receptorblokkers wat gebruik word om jou bloeddruk te beheer. Vra jou dokter as jy nie seker is nie
- ACE-remmers/ angiotensien-receptorblokkers (vir hoë bloeddruk) – dit kan akute nierbesering (ANB) veroorsaak, veral as jy bejaard is, jou nie behoorlik werk nie, jy watertablette neem, NSAID's neem of ontwater is (sien Moenie BIOTECH CIPROFLOXACIN neem nie)
- anti-distrimiese medisyne: medisyne wat jou hartritmte kan verander (bv. kinidien, hidrokidien, disopiramied, amiodaroon, sotalol, dofetilied, ibutilied, trisikliese antidepressante, sommige antimikrobiële middels (wat aan die groep makroliede behoort), sommige antipsigotiese middels
- probenesens (vir jig)
- metoklopramide (vir naardheid en braking)
- Moenie BIOTECH CIPROFLOXACIN en 'n medisyne genaamd tisanidien saam neem nie, dit kan lae bloeddruk en slaperigheid veroorsaak (sien Moenie BIOTECH CIPROFLOXACIN neem nie)
- Gelykydig gebruik van BIOTECH CIPROFLOXACIN en metotreksaat (gebruik in sekere tipes kanker, psoriase, rumatoïde artritis) kan lei tot verhoogde bloedvlakte van metotreksaat en verhoogde risiko van metotreksaat-toxisiteit. Gelykydig gebruik word nie aanbeveel nie
- Gelykydig gebruik van BIOTECH CIPROFLOXACIN met teofilien ('n medisyne wat vir asma gebruik word) kan 'n verhoging in die teofilienplasmakonsentrasies veroorsaak. As gevolg hiervan, kan jy meer teofilien-verwante newe-effekte ervaar
- Indien jy fenitoïen vir epilepsie gebruik, sal gelykydig gebruik met BIOTECH CIPROFLOXACIN laer fenitoïen bloedplasmakonsentrasies tot gevolg hê. Jou dokter moet jou fenitoïen dosis monitor nadat jy BIOTECH CIPROFLOXACIN behandel gestaan het
- Siklosporien (vir veltoestande, rumatoïde artritis en in orgaanplantings)
- Medisyne wat gebruik word om jou bloed te verhoed om te stol soos vitamine K antagonistie (bv warfarien, asenokoumarol, fenprocoumon of fluindion) of ander orale antikoagulantie (om die bloed te verdun) /ropinirool (vir Parkinson se siekte)
- klopsapien (antipsigotika)
- BIOTECH CIPROFLOXACIN mag die bloedvlakte van solpide (vir slaapversteurings) verhoog, daarom word gelykydig gebruik nie aanbeveel nie
- Gelykydig gebruik van nie-steroidiese antiinflammatoriese middels soos fenbufeen mag die risiko vir aanvalle/ stuiprekings verhoog. Die gelykydigheid toediening van BIOTECH CIPROFLOXACIN en warfarien mag die kans vir bloeding verhoog
- Indien jy 'n diabeet is en glibenklamied saam met BIOTECH CIPROFLOXACIN neem, wat hipoglisemie (lae bloedsuiker) kan veroorsaak.

## BIOTECH CIPROFLOXACIN mag die vlakte van die volgende medisyne in jou bloed verhoog:

- Pentoksifillien (vir bloedsomloopversteurings), kafeïne
- duloksetien (vir depressie, diabetiese senueweeskade of inkontinenzie)
- lidokaien (vir harttoestande of narcose gebruik)
- sildenafil (bv vir erectiele disfunksie)
- agomelation (vir depressie)

## Sekere medisyne verlaag die effek van BIOTECH CIPROFLOXACIN:

- Medisyne wat sukrafaat of yster bevat en teensuurmiddels verlaag die absorpsië van BIOTECH CIPROFLOXACIN wat minder effektief maak. Indien jy hierdie produktes moet gebruik, gebruik dit 2 ure na of voor dat jy BIOTECH CIPROFLOXACIN neem
- omeprasoel

## BIOTECH CIPROFLOXACIN tablette met kos en drank

Jy kan BIOTECH CIPROFLOXACIN met etes of op 'n leë maag neem. Moet egter NIE BIOTECH CIPROFLOXACIN met suwelprodukte of kalsiumaangevulde sappe alleenlik neem nie. Groot hoeveelhede suwelprodukte, veral melk of jogurt mag die opname van BIOTECH CIPROFLOXACIN vertraag, daarom moet siprofloxasien, soos bevat in BIOTECH CIPROFLOXACIN, 1 of 2 ure voor of ten minste 4 ure na hierdie produktes geneem word.

## Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om 'n baba te hé, raadpleeg asseblief jou dokter, apoteker of ander gesondheidsorgverskaffer vir advies voordat jy BIOTECH CIPROFLOXACIN neem. BIOTECH CIPROFLOXACIN met nie gebruik word as jy swanger is of borsvoed nie.

## Bestuur en die gebruik van masjiene

BIOTECH CIPROFLOXACIN mag jou vermoë om te bestuur of om masjienerie te hanter benadeel, veral wanneer jy gelykydig alkoholinname het. BIOTECH CIPROFLOXACIN mag jou minder waaksam laat voel. Sommige neurologiese ongewenste effekte kan voorkom.

Dit is nie altyd moontlik om te voorspel tot watter mate BIOTECH CIPROFLOXACIN mag inmeng met die daagliks aktiwiteit van 'n pasiënt nie. Jy moet verseker dat jy nie 'n voertuig bestuur of masjienerie hanter totdat jy bewus is van die mate waartoe BIOTECH CIPROFLOXACIN jou affekteer nie.

## 3. Hoe om BIOTECH CIPROFLOXACIN te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd BIOTECH CIPROFLOXACIN presies soos jou dokter of apoteker jou opdrag gegee het. Raadpleeg jou dokter of apoteker indien jy nie seker is nie.

Jou dokter sal besluit hoe lank jou behandeling sal duur. Jou dokter sal aan jou verduidelik presies hoeveel BIOTECH CIPROFLOXACIN jy sal moet neem asook hoe gereeld en vir hoe lank. Dit sal afhang van die tipe en erns van jou infeksie. Die gewone behandelingstydperk is 5 tot 10 dae.

Vir ernstige en gekompliseerde infeksies sal langer terapie dalk nodig wees.

Die doseringssreks is 250 – 750 mg twee keer per dag. Die tablet moet heel gesluk word met genoegsame vloeistof en kan met of sonder voedsel geneem word.

- Ernstige en/ of gekompliseerde infeksies van die lae respiratoriese kanaal:  
750 mg twee keer per dag

- Ernstige en/ of gekompliseerde aansteeklike diarree:  
500 mg twee keer per dag

- Ernstige en/ of gekompliseerde infeksie van die ureinweg:  
500 mg twee keer per dag

Vir die voorkoming van indringende infeksies van *Neisseria meningitidis*, neem 'n enkeldosis van 500 mg.

## Bejaardes

Bejaarde pasiënte moet 'n dosis so laag as moontlik ontvang afhangende van die erns van hul siekte en hoe goed hul niere werk.

## Indien jy meer BIOTECH CIPROFLOXACIN neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apoteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

## Indien jy vergeet om BIOTECH CIPROFLOXACIN te neem as wat jy moet

Moenie 'n dubbele dosis neem om op te maak vir die vergeet individuele dosisse nie. Hou aan om die volgende tablet op die gewone tyd te neem. Indien jy sukkel om te onthou wanneer jy jou medisyne moet neem, vra jou apoteker vir wenke.</