SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
BIOTECH CIPROFLOXACIN 250 (Film coated tablets)
BIOTECH CIPROFLOXACIN 500 (Film coated tablets)

COMPOSITION:
BIOTECH CIPROFLOXACIN 250: Each film coated tablet contains ciprofloxacin hydrochloride equivalent to 250 mg ciprofloxacin.
BIOTECH CIPROFLOXACIN 500: Each film coated tablet contains ciprofloxacin hydrochloride equivalent to 500 mg ciprofloxacin.
Excipients:
Core: Pregelatinised starch, microcrystalline cellulose, colloidal silicon dioxide, crospovidone, and magnesium stearate.
Film-coating: Opadry Y-1-7000 White consisting of hypromellose 2910, titanium dioxide and polyethylene glycol 4000.
Sugar free.

PHARMACOLOGICAL CLASSIFICATION:
A 20.1.1 Broad and medium spectrum antibiotics

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Ciprofloxacin is a synthetic fluoroquinolone antibiotic. It is bactericidal and acts by inhibiting the A subunit of DNA-gyrase which is essential in the reproduction of bacterial DNA.
Pharmacokinetic properties
After oral administration, ciprofloxacin plasma levels are dose-related and peak at 0,5 – 2 hours.
The absolute bioavailability is approximately 70 %. Protein binding is 40 %. Forty to fifty percent is excreted in urine as unchanged ciprofloxacin. Approximately 15 % of a single dose is eliminated as metabolites. Elimination is primarily renal and mainly during the first 12 hours after dosing. Renal clearance is approximately 300 ml/min.
The elimination half-life of unchanged ciprofloxacin is 3 – 5 hours. The elimination kinetics is linear.
Micro-organisms resistant to ciprofloxacin:
Enterococcus faecium; Norcardia asteroides; Ureaplasma urealyticum; Peptostreptococcus species; *Peptococcus* species; Bacteroides; *Treponema pallidum*

INDICATIONS:
BIOTECH CIPROFLOXACIN is indicated for the treatment of the following infections, when caused by susceptible organisms:
Lower Respiratory Tract Infections caused by:
Enterobacter cloacae, Escherichia coli, Haemophilus influenza, Haemophilus parainfluenzae, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa.
Urinary tract infections caused by:
Citrobacter diversus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Providencia rettgeri, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus faecalis.
Skin and soft tissue infections caused by:
Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes.
Gastrointestinal infections:
Infective diarrhoea caused by *Campylobacter jejuni, Escherichia coli, Shigella flexneri and Shigella sonnei.*
Bone infections:
Osteomyelitis due to susceptible Gram-negative organisms.
Gonorrhoea

CONTRAINDICATIONS:
BIOTECH CIPROFLOXACIN is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, any other quinolones, or any of the inactive ingredients.
Pregnancy and lactation.
BIOTECH CIPROFLOXACIN is contraindicated in children under the age of 18 years.
Experimental evidence indicates lesions of the cartilage of weight-bearing joints in immature members of certain animal species.

WARNINGS and SPECIAL PRECAUTIONS:
BIOTECH CIPROFLOXACIN should be used with caution in patients with a history of convulsive disorders.
Crystalloid related to the use of BIOTECH CIPROFLOXACIN has been observed. Patients receiving BIOTECH CIPROFLOXACIN should be well hydrated and excessive alkalinity of the urine should be avoided
In the treatment of infections caused by *Pseudomonas aeruginosa*, an aminoglycoside must be administered concomitantly (See DOSAGE AND DIRECTIONS FOR USE).
Long-term or repeated administration of BIOTECH CIPROFLOXACIN can lead to superinfections with resistant bacteria or fungi.
Effect on the ability to drive and use machines:
The ability to drive a motor vehicle or operate machinery may be impaired by BIOTECH CIPROFLOXACIN. This applies particularly in combination with alcohol.

INTERACTIONS:
Concurrent administration of BIOTECH CIPROFLOXACIN with theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline-related toxicity. If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate.
BIOTECH CIPROFLOXACIN tablets should be administered 1 - 2 hours before, or at least 4 hours after taking iron preparations, antacids containing magnesium, aluminium, calcium or sucralfate, as interference with absorption may occur. This restriction does not apply to antacids belonging to the class of H2-receptor blockers.
Concomitant administration of the non-steroidal anti-inflammatory medicine fenbufen with quinolones may increase the risk of central nervous system stimulation and seizures.
Monitoring of serum creatinine concentrations is advised in patients on concomitant cyclosporine therapy, as transient increases in serum creatinine concentrations have been observed.
The simultaneous administration of BIOTECH CIPROFLOXACIN and warfarin may lead to warfarin toxicity; therefore the INR should be closely monitored.
Concurrent administration of BIOTECH CIPROFLOXACIN and glibenclamide can potentiate the action of glibenclamide, leading to hypoglycaemia.
Probenecid interferes with renal secretion of BIOTECH CIPROFLOXACIN. Co-administration of probenecid and BIOTECH CIPROFLOXACIN increases the BIOTECH CIPROFLOXACIN serum concentrations.
Metoclopramide accelerates the absorption of BIOTECH CIPROFLOXACIN, resulting in shorter time to reach maximum plasma concentrations.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE:
In the treatment of infections caused by *Pseudomonas aeruginosa*, an aminoglycoside must be administered concomitantly.
BIOTECH CIPROFLOXACIN TABLETS:
BIOTECH CIPROFLOXACIN tablets should be swallowed whole with plenty of liquid and may be taken with or without meals.
Dosage and Duration of Treatment
The dosage range is 250 – 750 mg twice daily. The duration of treatment depends upon the severity of the infection, clinical response and bacteriological cultures. For acute uncomplicated cystitis in women, the treatment period is 3 days. Generally, treatment should be continued for at least 3 days after the signs and symptoms of the infection have disappeared. For acute infections the usual treatment period is 5 – 10 days with BIOTECH CIPROFLOXACIN tablets. For severe and complicated infections more prolonged therapy may be required.
In streptococcal infections the treatment must last at least 10 days.

Infections of the lower respiratory tract

Mild to moderate:	250 – 500 mg twice daily
Severe or complicated:	750 mg twice daily
In cystic fibrosis patients:	750 mg twice daily. The low body mass of these patients should, however, be taken into consideration when determining dosage (7,5 to 15 mg/kg/day).

Infections of the urinary tract

Acute uncomplicated cystitis:	250 mg twice daily
Mild to moderate:	250 mg twice daily
Severe or complicated:	500 mg twice daily

Infections of the skin

Mild to moderate:	500 mg twice daily
Severe or complicated:	750 mg twice daily
Infectious diarrhoea:	500 mg twice daily

Bone infections

Mild to moderate:	500 mg twice daily
Severe or complicated:	750 mg twice daily

Treatment may be required for 4 – 6 weeks or longer.

Gonorrhoea A single dose of 250 mg.
Elderly patients should be treated with the lowest possible dose.

Impaired Renal or Liver Function
In patients with reduced renal function, the half-life of ciprofloxacin may be prolonged. The dosage needs to be adjusted as shown below.
For patients with renal impaired and hepatic insufficiency, monitoring of medicine serum levels provides the most reliable basis for dose adjustment.

Dose adjustment of ciprofloxacin for patients with renal or hepatic impairment

1.	**Kidney insufficiency:**	
1.1	$CL_{cr} \geq 31$ mL/min/1,73 m^2	Max 800 mg/day intravenously
1.2	$CL_{cr} \leq 30$ mL/min/1,73 m^2	Max 400 mg/day intravenously
1.3	Impaired renal function and haemodialysis	As in 1.2 above; after dialysis on dialysis days.
2.	**Renal impairment and CAPD** (Chronic ambulatory peritoneal dialysis):	
2.1	Oral administration of either BIOTECH CIPROFLOXACIN tablet as 500 mg tablet or 2 x 250 mg tablets is indicated	
2.2	For CAPD patients with peritonitis, the recommended daily oral dose is 500 mg four times a day.	
3.	**Hepatic impairment:**	No dose adjustment
4.	**Hepatic and renal impairment:**	As in 1.1 and 1.2 above

SIDE EFFECTS:
Gastrointestinal system – *Incidence more frequent*
Nausea, diarrhoea, vomiting, dyspepsia, abdominal pain. The development of severe and persistent diarrhoea may indicate pseudomembranous colitis, requiring immediate treatment. In such cases BIOTECH CIPROFLOXACIN must be discontinued and appropriate therapy initiated (e.g. vancomycin, orally 4 x 250 mg/day).
Vision – *Incidence less frequent or rare*
Visual disturbances (e.g. diplopia, colour vision).
Hearing and vestibular disorders – *Incidence rare*
Tinnitus, transient impairment of hearing – especially at high frequencies.
Haematological system - *Incidence rare*
Eosinophilia, leucopenia, granulocytopenia, anaemia, thrombocytopenia, leucocytosis, thrombocytosis, haemolytic anaemia, altered prothrombin values.
Skin - *Incidence less frequent*
Rashes
Less frequent: Urticaria and photosensitivity (blisters, sensation of skin burning), erythema nodusum and erythema exsudativum multiforme (minor) have been reported.
The following have been reported: Stevens-Johnson syndrome, Lyell's syndrome, punctate skin haemorrhages (petechiae), haemorrhagic bullae and papules with signs of vascular involvement (vasculitis).
Central Nervous System
More frequent: Dizziness, headache, tiredness, nervousness, agitation and trembling
Less frequent: Insomnia, peripheral paralgesia, sweating, unsteady gait, convulsions, increase in intracranial pressure, anxiety states, nightmares, confusion, hallucinations, psychotic reactions (even progressing to self-endangering behaviour), depression.
In some instances, these reactions occurred after the first administration of ciprofloxacin. In these cases BIOTECH CIPROFLOXACIN must be discontinued and the medical practitioner informed immediately.
Musculoskeletal disorders
Joint pain, joint swelling.
Less frequent: general feeling of weakness, and myalgia (which may be of special importance in patients with myasthenia gravis) and tendosynovitis have been observed. Cases of achillotendinitis have been observed. Partial or complete rupture of the Achilles tendon occurred in predominantly elderly patients on treatment with systemic glucocorticoids. At any sign of an achillotendinitis (or any tendonitis) (e.g. painful swelling) the administration of BIOTECH CIPROFLOXACIN should be discontinued and a medical practitioner should be consulted.
Cardiovascular system – *Incidence rare*
Tachycardia, flushing, migraine, syncope.
Genitourinary system – *Incidence rare*
Crystalloid related to the use of ciprofloxacin has been observed. Patients receiving BIOTECH CIPROFLOXACIN should be well hydrated and excessive alkalinity of the urine should be avoided.
Interstitial nephritis, transient renal impairment including transient renal failure, and haematuria have been reported.
Hypersensitivity reactions – *Incidence rare*
Anaphylactic/anaphylactoid reactions can occur (e.g. facial, vascular and laryngeal oedema, dyspnoea progressing to life-threatening shock), in some instances after the first administration. In these cases BIOTECH CIPROFLOXACIN has to be discontinued and appropriate medical treatment instituted.
Local reactions – *Incidence rare*
Phlebitis or thrombophlebitis, local irritation and pain at the site of injection. Intravenous infusion should be administered by slow infusion over a period of 60 minutes. These reactions are more frequent if the infusion time is 30 minutes or less, or if small veins of the hand are used. These may appear as local skin reactions, which resolve rapidly upon completion of the infusion. Subsequent intravenous administration is not contraindicated unless the reactions recur or worsen.
Influence on laboratory parameters / urinary sediment
There can be temporary elevations of transaminases, alkaline phosphatase or cholestatic jaundice, (especially in patients with liver damage, temporary increase in urea, creatinine or hyperbilirubinaemia).
Other
Impaired taste and smell, hyperglycaemia. Hepatic necrosis, very seldom progressing to hepatic failure, has been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In the event of acute, excessive oral overdosage, reversible renal toxicity has been reported.
Apart from routine emergency measures, it is recommended to monitor renal function and to administer magnesium- or calcium-containing antacids which reduce the absorption of oral BIOTECH CIPROFLOXACIN.
Only a small amount of ciprofloxacin (< 10 %) is removed from the body after haemodialysis or peritoneal dialysis.
Treatment is symptomatic and supportive.

IDENTIFICATION:
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.

PRESENTATION:
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.

All pack sizes may not necessarily be marketed at one time.

STORAGE INSTRUCTIONS:
Store in a cool, dry place at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
BIOTECH CIPROFLOXACIN 250: A40/20.1.1/0368
BIOTECH CIPROFLOXACIN 500: A40/20.1.1/0369

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date on the registration certificate: 12 June 2009
Date of the most recently revised package insert: 12 June 2009
Date of notification with regard to amended Reg. 9 and 10: 02 February 2015

SKEDULERINGSTATUS:
S4

EIENDOMSNAAM EN DOSEERVORM:
BIOTECH CIPROFLOXACIN 250 (Filmbedekte tablette)
BIOTECH CIPROFLOXACIN 500 (Filmbedekte tablette)

SAMETSTELLING:
BIOTECH CIPROFLOXACIN 250: Elke filmbedekte tablet bevat siprofloksasienhidrochloried ekwivalent aan 250 mg siprofloksasien.
BIOTECH CIPROFLOXACIN 500: Elke filmbedekte tablet bevat siprofloksasienhidrochloried ekwivalent aan 500 mg siprofloksasien.
Hulpstoffen:
Kern: Pregelatinized stysel, mikrokristallyne sellulose, kolloïdale silikondioksied, crospovidone, en magnesiumstearaat.
Film-laag: Opadry Y-1-7000 Wit bestaan uit hypromellose 2910, poliëtileen glikol 400, titaandioksied en poliëtileen glikol 4000.
Suikervry

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.1.1 Breë-en mediumspektrumantibiotika

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskap
Siprofloksasien is 'n sintetiese fluoro-kinoloon. Dit is bakteriedodend en werk deur inhibisie van die A sub-eenheid van DNA-girase wat essensieël is vir die reproduksie van bakteriële DNA.
Farmakokinetiese eienskappe
Na orale toediening is siprofloksasien plasmavlakke dosis verwant en dit piek teen 0,5 – 2 ure.
Die absolute biobeskikbaarheid is ongeveer 70 %. Proteiënbinding is 40 %. Veertig tot vyftig persent word uitgeskei in die urien as onveranderde siprofloksasien. Ongeveer 15 % van 'n enkeldosis word as metaboliete uitgeskei. Uitskeiding geskied hoofsaaklik deur die niere en veral gedurende die eerste 12 uur na dosering. Renale opruiming is ongeveer 300 ml/min.
Die eliminasie-halflewe van onveranderde siprofloksasien is 3 – 5 ure. Die eliminasie-kinetika is lineêr.
Mikro-organismes weerstandig teen siprofloksasien:
Enterococcus Faecium; Nocardia asteroides; Ureaplasma urealyticum; Peptostreptococcus spesies; *Peptococcus spesies; Bacteroides; Treponema pallidum*

INDIKASIES:
BIOTECH CIPROFLOXACIN is aangedui vir die behandeling van die volgende infeksies; indien deur sensitiewe bakterieë veroorsaak:
Onderste Lugweginfeksies veroorsaak deur:
Enterobacter cloacae, Escherichia coli, Haemophilus influenza, Haemophilus parainfluenzae, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa.
Urienweginfeksies veroorsaak deur:
Citrobacter diversus, Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Providencia rettgeri, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus faecalis.
Vel- en sagte weefselinfeksies veroorsaak deur:
Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes.
Gastro-intestinale infeksies:
Infektiewe diarree veroorsaak deur *Campylobacter jejuni, Escherichia coli, Shigella flexneri* en *Shigella sonnei.*
Beeninfeksies:
Osteomiëlitis as gevolg van vatbare Gram-negatiewe organismes.
Gonorree

KONTRA-INDIKASIES:
BIOTECH CIPROFLOXACIN is teenaangedui in pasiënte met 'n geskiedenis van hipersensitiwiteit vir siprofloksasien, ander kinolone of enige van die onaktiewe bestanddele.
Swangerskap en laktasie.
BIOTECH CIPROFLOXACIN is teenaangedui in kinders jonger as 18 jaar.
Eksperimentele gegewens toon dat letsels van die kraakbeen van gewigdraende gewrigte by onvolwasse lede van sekere diersoorte waargeneem is.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
BIOTECH CIPROFLOXACIN moet met omsigtigheid gebruik word in pasiënte met 'n geskiendenis van konvulsiewe toestande.
Kristalurie, geassosieer met die gebruik van BIOTECH CIPROFLOXACIN, is waargeneem. Pasiënte wat BIOTECH CIPROFLOXACIN ontvang moet 'n goeie inname van vloeistof handhaaf en oormatige alkaliniteit van die uriene moet vermy word.
In die behandeling van infeksies veroorsaak deur *Pseudomonas aeriginosa*, moet 'n aminoglikosied gesamentlik toegedien word. (Sien DOSIS EN GEBRUIKSAANWYSINGS).
Langtermyn of herhaalde toediening van BIOTECH CIPROFLOXACIN kan tot superinfeksies met weerstandige bakterieë of swamme.
Uitwerking op die vermoë om te bestuur en gebruik masjiene:
Die vermoë om 'n voertuig te bestuur of masjinerie te hanteer kan belemmer word deur die gebruik van BIOTECH CIPROFLOXACIN. Dit geld veral wanneer die middel saam met alkohol geneem word.

INTERAKSIES:
Gelyktydige toediening van BIOTECH CIPROFLOXACIN met teofillien kan lei tot verhoogde plasmavlakke en verlenging van teofillien se eliminasie-halfleeftyd. Dit kan 'n verhoogde risiko in teofillienverwante newe-effekte tot gevolg hê. Indien gelyktydige gebruik nie vermy kan word nie, moet teofillien se plasmavlakke gemonitor word en dosisaanpassings, soos nodig, gemaak word.
BIOTECH CIPROFLOXACIN tablette moet 1 - 2 ure voor, of ten minste 4 ure nadat ysterpreparate, teensuurmiddels wat magnesium, aluminium, kalsium of sukralfaat bevat, geneem word, aangesien bogenoemde middels die absorpsie kan beïnvloed. Hierdie beperking geld nie vir teensuurmiddels wat tot die H2-reseptor-blokkeerders klas behoort nie.
Gesamentlike toediening van die nie-steroïdale anti-inflammatoriese middel fenbufen met kinolone mag die risiko vir sentrale senuweestelsel stimulasie en konvulsies verhoog.
Dit word aanbeveel dat serumkreatinienkonsentrasies in pasiënte wat gelyktydig met siklosporien behandel word, gemonitor moet word aangesien 'n verbygaande verhoging in serumkreatinienkonsentrasies in hierdie pasiënte waargeneem is.
Die gelyktydige toediening van BIOTECH CIPROFLOXACIN en warfarien mag aanleiding gee tot warfarien toksisiteit; daarom moet die INR nou gekontrolleer word.
Die gelyktydige toediening van BIOTECH CIPROFLOXACIN en glibenklamied kan die werking van glibenklamied verhoog, wat kan lei tot hipoglisemie.
Probenesied versteur die renale uitskeiding van BIOTECH CIPROFLOXACIN. Gelyktydige toediening van probenesied en BIOTECH CIPROFLOXACIN verhoog BIOTECH CIPROFLOXACIN serumkonsentrasies.
Metoklopramied versnel die absorpsie van BIOTECH CIPROFLOXACIN , wat veroorsaak dat maksimum plasmavlakke vinniger bereik word.

SWANGERSKAP EN LAKTASIE:
Veiligheid tydens swangerskap en laktasie is nie vasgestel nie (sien KONTRA-INDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS:
In die behandeling van infeksies veroorsaak deur *Pseudomonas aeruginosa*, moet 'n aminoglikosied gesamentlik toegedien word.
BIOTECH CIPROFLOXACIN TABLETTE:
BIOTECH CIPROFLOXACIN tablette moet heel ingesluk word met voldoende vloeistof en mag met of sonder etes geneem word.
Dosis en behandelingsperiode
Die dosisgrense is 250 – 750 mg twee maal per dag. Die duur van behandeling hang af van die graad van ernstigheid van die infeksie, kliniese reaksie en bakteriologiese kulture. Vir akute, ongekompliseerde sistitis in vroue is die behandelingsperiode 3 dae. Gewoonlik moet daar met behandeling voortgegaan word vir ten minste 3 dae nadat die tekens en simptome van die infeksie opgeklaar het. Vir akute infeksies is die normale behandelingsperiode 5 – 10 dae met BIOTECH CIPROFLOXACIN tablette. Vir ernstige en gekompliseerde infeksies kan 'n langer behandelingsperiode benodig word.
In streptokokkale infeksies moet die behandeling vir ten minste 10 dae duur.

Onderste Lugweginfeksies

Gering tot matig:	250 – 500 mg twee maal per dag
Ernstig of gekompliseerd:	750 mg twee maal per dag
In pasiënte met sistiese fibrose:	750 mg twee maal per dag. Die lae liggaamsmassa van hierdie pasiënte moet egter in ag geneem word wanneer die dosis bepaal word (7,5 tot 15 mg/kg/dag).

Urienweginfeksies

Akute, ongekompliseerde sistitis:	250 mg twee maal per dag
Gering tot matig:	250 mg twee maal per dag
Ernstig of gekompliseerd:	500 mg twee maal per dag

Velinfeksies

Gering tot matig:	500 mg twee maal per dag
Ernstig of gekompliseerd:	750 mg twee maal per dag
Infektiewe diarree:	500 mg twee maal per dag

Beeninfeksies

Gering tot matig:	500 mg twee maal per dag
Ernstig of gekompliseerd:	750 mg twee maal per dag

Behandeling mag benodig word vir 4 – 6 weke of selfs langer.

Gonorree 'n Enkeldosis van 250 mg.
Bejaarde pasiënte moet met die laagste moontlike dosering behandel word.

Ingekorte nier- of lewerfunksie
Die halfleeftyd van siprofloksasien kan verleng wees in pasiënte met verminderde nierfunksie. Die dosering moet aangepas word soos onder aangedui.
Vir pasiënte met ingekorte nierfunksie en lewerontoereikendheid, bied monitering van die geneesmiddel se serumvlakke die mees betroubare basis vir dosisaanpassing.

Dosisaanpassing van siprofloksasien in pasiënte met ingekorte nier – of lewerfunksie

1. Nierontoereikendheid:	
1.1 $Cl_{cr} \geq 31$ mL/min/1,73 m^2	Maks 800 mg/dag intraveneus
1.2 $Cl_{cr} \leq 30$ mL/min/1,73 m^2	Maks 400 mg/dag intraveneus
1.3 Ingekorte nierfunksie en hemodialise	Soos 1.2 hierbo; op dialise dae na dialise
2. Ingekorte nierfunksie en KAPD (Kroniese ambulante peritoneale dialise):	
2.1 Orale toediening van of BIOTECH CIPROFLOXACIN tablette as 500 mg tablet of 2 x 250 mg tablette is aangedui.	
2.2 Vir KAPD pasiënte met peritonitis is die aanbevole daaglike orale dosis 500 mg vier maal per dag.	
3. Lewerinkorting:	Geen dosisaanpassing
4. Lewer- en nierinkorting:	Soos 1.1 en 1.2 hierbo

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Newe-effekte
Gastro-intestinale sisteem – *Voorkoms meer gereeld*
Naarheid, diarree, braking, dispepsie, abdominale pyn. Die ontwikkeling van ernstige en aanhoudende diarree mag dui op pseudomembraneuse kolitis wat onmiddelike behandeling vereis. In so 'n geval moet BIOTECH CIPROFLOXACIN gestaak word en met toepaslike behandeling begin word (bv. vankomisien, oraal, 4 x 250 mg/dag).
Gesig – *Voorkoms minder gereeld of selde*
Versteurde visie (bv. diplopie, kleurwaarneming).
Gehoor en vestibulêre versteurings – *Voorkoms selde*
Tinnitus, verbygaande gehoorverswakking – veral by hoë frekwensies.
Hematologiese sisteem – *Voorkoms selde*
Eosinofilie, leukositopenie, granulositopenie, anemie, trombositopenie, leukositose, trombositose, hemolitiese anemie, veranderde protrombienwaardes.
Vel – *Voorkoms minder gereeld*
Uitslag
Minder gereeld: Urtikaria en fotosensitiwiteit (blase, gevoel van velbrand), erythema nodusum en erythema exsudativum multiforme (minor) is aangemeld.
Die volgende is aangemeld: Stevens-Johnson se sindroom, Lyell se sindroom, punktaat velbloedings (petegia), blaasvorming met meegaande bloeding (hemoragiese bullae) en klein nodules (papulae) met korsvorming wat vaskulêre betrokkenheid (vaskulitis) aandui.
Sentrale Senuweestelsel
Meer gereeld: Duiseligheid, hoofpyn, moegheid, senuagtigheid, rusteloosheid en bewing.
Minder gereeld: Slaaploosheid, perifere paralgesie, sweet, wankelende gang, konvulsies, toename in intrakraniale druk, angstoestande, nagmerries, verwardheid, hallusinasies, psigotiese reaksies (wat selfs kan ontwikkel tot gedrag wat die persoon in gevaar stel), depressie.
In sommige gevalle het hierdie reaksies reeds na die eerste toediening van siprofloksasien voorgekom. In sulke gevalle moet behandeling met BIOTECH CIPROFLOXACIN gestaak word en die geneesheer moet onmiddelik ingelig word.
Spier- en skeletversteurings
Gewrigspyn en -swelling.
Minder gereeld: algemene gevoel van swakheid en mialgie (wat veral van belang is in pasiënte met myasthenia gravis) en tendosinovitis is al waargeneem. Gevalle van achillotendinitis is al waargeneem. Gevalle van gedeeltelike of algehele skeuring van die achillestendon is veral in bejaardes wat vooraf met glukokortikosteroïde behandel is, gerapporteer. Met enige teken van achillotendinitis (of enige tendinitis) (bv. pynlike swelling) moet die toediening van BIOTECH CIPROFLOXACIN gestaak word en 'n geneesheer moet geraadpleeg word.
Kardiovaskulêre sisteem – *Voorkoms selde*
Tagikardie, gloede, migraine, floutes.
Genito-urinêre sisteem – *Voorkoms selde*
Kristalloïd, verwant aan die gebruik van siprofloksasien is al waargeneem. Pasiënte wat BIOTECH CIPROFLOXACIN neem moet voldoende vloeistof inneem en oormatige alkaliniteit van die uriene moet vermy word.
Interstisiële nefritis, verbygaande nierinkorting insluitende verbygaande nierversaking en hematurie is gerapporteer.
Hipersensitiwiteitsreaksies – *Voorkoms selde*
Anafilaktiese/anafilaktoïede reaksies kan voorkom (bv. Gesigs-, vaskulêre en laringeale edeem , dispnee wat ontwikkel tot lewensbedreigende skok), in sommige gevalle reeds na die eerste toediening. In sulke gevalle moet behandeling met BIOTECH CIPROFLOXACIN gestaak word en mediese behandeling gegee word.
Lokale reaksies – *Voorkoms selde*
Flebitis of tromboflebitis, lokale irritasie en pyn by die plek van inspuiting. Intraveneuse infusie moet toegedien word deur stadige infusie oor 'n tydperk van 60 minute. Hierdie reaksies is meer algemeen indien die infusie tyd 30 minute of minder is, of indien klein venae van die hand gebruik word. Hierdie mag voorkom as lokale velreaksies wat vinnig opklaar sodra die infusie voltooi is. Daaropvolgende intraveneuse toediening is nie teenaangedui nie tensy die reaksies weer voorkom of vererger.
Invloed op laboratorium uitslae / urinêre sediment
Daar kan 'n tydelike verhoging in transaminase, alkaliese fosfatase of cholestatiese geelsug voorkom, (veral in pasiënte met lewerskade, tydelike toename in ureum, kreatinien of hiperbilirubinemie).
Ander
Ingekorte smaak en reuk, hiperglisemie. Lewernekrose, wat selde vorder tot lewerversaking, is gerapporteer.
Langtermyn of herhaalde toediening van BIOTECH CIPROFLOXACIN kan tot superinfeksies met weerstandbiedende bakterieë of swamme lei.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Omkeerbare niertoksisiteit is in gevalle van akute, oormatige orale oordosering gerapporteer.
Dit word aanbeveel om benewens roetine noodbehandeling, ook nierfunksie te monitor en om magnesium- of kalsium-bevattende teensuurmiddels wat die absorpsie van orale BIOTECH CIPROFLOXACIN verminder, toe te dien .
Slegs 'n klein hoeveelheid siprofloksasien (< 10 %) word na hemodialise of peritoneale dialise uit die liggaam verwyder.
Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
BIOTECH CIPROFLOXACIN 250: Wit, bikonvekse, ronde filmbedekte tablette, waarop NJB aan die een kant en 250 aan die ander kant verskyn.
BIOTECH CIPROFLOXACIN 500: Wit, bikonvekse, kapsule-vormige filmbedekte tablette, waarop NJB aan die een kant en 500 aan die ander kant verskyn.

AANBIEDING:
BIOTECH siprofloksasien 250 en 500 is beskikbaar in een van die volgende aan te bied:
- Wit HDPE houers wat 50 of 100 tablette.
- Transparante PVC en silwer aluminium blister stroke met 10 tablette per strook en 1 strook per buitenste karton.

Alle verpakkings groottes mag nie noodwendig op een slag bemark word nie.

BERGINGSAANWYSINGS:
Bewaar teen of benede 25 ° C, in 'n koel droë plek.
HOU BUITE BEREIK VAN KINDERS

REGISTRASIENOMMER:
BIOTECH CIPROFLOXACIN 250: A40/20.1.1/0368
BIOTECH CIPROFLOXACIN 500: A40/20.1.1/0369

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN REGISTRASIE SERTIFIKAAT:
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Suid Afrika

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