

DYNAFLOC 250

DYNAFLOC 500

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

DYNAFLOC 250 (tablets)

DYNAFLOC 500 (tablets)

COMPOSITION:

Each DYNAFLOC 250 tablet contains ciprofloxacin hydrochloride monohydrate, equivalent to 250 mg ciprofloxacin.

Each DYNAFLOC 500 tablet contains ciprofloxacin hydrochloride monohydrate, equivalent to 500 mg ciprofloxacin.

PHARMACOLOGICAL CLASSIFICATION:

A: 20.1.1. Broad and medium spectrum antibiotics.

PHARMACOLOGICAL ACTION:

Ciprofloxacin is a synthetic, 4-quinolone derivative with *in vitro* bactericidal activity against the following Gram-negative and Gram-positive organisms. *In vitro* sensitivity does not necessarily imply *in vivo* efficacy.

<i>Acinetobacter</i>	<i>Haemophilus influenzae</i>	<i>Proteus vulgaris</i>	<i>Streptococcus</i>
<i>Aeromonas</i>	<i>Haemophilus para-influenzae</i>	<i>Providencia rettgeri</i>	<i>pyogenes</i>
<i>Brucella</i>	<i>Hafnia</i>	<i>Providencia stuartii</i>	<i>Streptococcus species</i>
<i>Campylobacter jejuni</i>	<i>Klebsiella species</i>	<i>Pseudomonas</i>	<i>Streptococci viridans</i>
<i>Citrobacter freundii</i>	<i>Listeria</i>	<i>aeruginosa</i>	<i>Vibrio</i>
<i>Citrobacter species</i>	<i>Moraxella catarrhalis</i>	<i>Salmonella enteritidis</i>	<i>Yersinia</i>
<i>Corynebacterium</i>	<i>Morganella morganii</i>	<i>Serratia marcescens</i>	
<i>E. coli</i>	<i>Neisseria gonorrhoea</i>	<i>Shigella flexneri</i>	
<i>Edwardsiella</i>	<i>Pasteurella</i>	<i>Shigella sonnei</i>	
<i>Enterobacter cloacae</i>	<i>Plesiomonas</i>	<i>Staphylococcus aureus</i>	
<i>Enterobacter species</i>	<i>Proteus mirabilis</i>	<i>Staphylococcus</i>	
		<i>epidermidis</i>	
		<i>Streptococcus faecalis</i>	

The following organisms show varying degrees of *in vitro* sensitivity to ciprofloxacin: *Alcaligenes*, *Enterococcus faecalis*, *Flavobacterium*, *Gardnerella*, *Legionella*, *Mycobacterium fortuitum*, *Mycobacterium tuberculosis*, *Mycoplasma hominis*, *Streptococcus agalactiae*, *Chlamydia*.

The following are usually resistant:

Enterococcus faecium, *Ureaplasma urealyticum*, *Nocardia asteroides*. With a few exceptions, anaerobes are moderately sensitive (e.g. *Peptococcus*, *Peptostreptococcus*) to resistant (e.g. *Bacteriodes*, *Treponema pallidum*).

Ciprofloxacin plasma levels are dose-related and peak 0,5 – 2 hours after oral dosing. The absolute oral bioavailability is approximately 70% with no substantial loss by first pass metabolism. Distribution of ciprofloxacin is wide and the volume of distribution high, indicating extensive tissue penetration. Ciprofloxacin is present in lung, skin, fat, muscle, cartilage and bone. It is also present in active form in the saliva, nasal and bronchial secretions, sputum, skin blister fluid, lymph, peritoneal fluid, bile secretions, prostatic secretions, cerebrospinal fluid and the aqueous humor. Protein binding is low. 40% to 50% is excreted in urine as unchanged drug. Approximately 15% of a single dose of ciprofloxacin is eliminated as metabolites. Elimination occurs primarily by the kidneys and mainly during the first 12 hours after dosing. Renal clearance is approximately 300 ml/minute. The elimination half-life of unchanged ciprofloxacin is 3 – 5 hours. The elimination kinetics are linear; after repeated dosing at 12 hourly intervals and once steady state has been reached no accumulation occurs.

INDICATIONS:

DYNAFLOC is indicated for the treatment of the following infections caused by ciprofloxacin sensitive bacteria:

Lower Respiratory Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae* and *Haemophilus parainfluenzae*.

Urinary Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter diversus*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis* and *Streptococcus faecalis*.

Skin and Soft Tissue Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Streptococcus pyogenes*.

Gastro-intestinal Infections: Infective diarrhoea caused by *E. coli*, *Campylobacter jejuni*, *Shigella flexneri* and *Shigella sonnei*.

Bone Infections: Osteomyelitis due to susceptible Gram-negative organisms.

Gonorrhoea.

DYNAFLOC is ineffective against *Treponema pallidum*.

In the treatment of infections caused by *Pseudomonas aeruginosa*, an aminoglycoside must be administered concomitantly.

CONTRA-INDICATIONS:

Safety during pregnancy and lactation has not been established.

DYNAFLOC is contra-indicated in children under 18 years and in growing adolescents, except where the benefits of treatment exceed the risks. Experimental evidence indicates that, species variable reversible lesions of the cartilage of weight bearing joints has been seen in immature members of certain animal species.

DYNAFLOC is contra-indicated in patients who have shown hypersensitivity to ciprofloxacin or any other quinolones.

WARNINGS:

DYNAFLOC should be used with caution in patients with a history of convulsive disorders.

Crystalluria related to the use of DYNAFLOC has been observed. Patients receiving DYNAFLOC should be well hydrated and excessive alkalinity of the urine should be avoided.

DOSAGE AND DIRECTIONS FOR USE:

DYNAFLOC 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 findings. 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 DYNAFLOC tablets. For severe and complicated infections more prolonged therapy may be required. In streptococcal infections the treatment must last at least 10 days because of the risk of late complications.

Infections of the lower respiratory tract: Mild to moderate – 250 to 500 mg twice daily; severe or complicated – 750 mg twice daily. In cystic fibrosis patients the dose is 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 receive a dose as low as possible; this will depend on the severity of the illness and on the creatinine clearance.

Impaired Renal or Liver Function:

In patients with reduced renal function, the half-life of ciprofloxacin is prolonged and the dosage needs to be adjusted.

For patients with changing renal function or patients with renal impairment and hepatic insufficiency, monitoring of drug serum levels provides the most reliable basis for dose adjustment.

Dose adjustment of ciprofloxacin for patients with kidney and/or liver insufficiency.

- | | |
|---|---|
| 1. Kidney insufficiency: | |
| 1.1 $CL_{Cr} \geq 31 \text{ ml/min/1,73 m}^2 \leq 60 \text{ ml/min/1,73 m}^2$ | Max 1000 mg/day orally. |
| 1.2 $CL_{Cr} \leq 30 \text{ ml/min/1,73 m}^2$ | Max 500 mg/day orally. |
| 1.3 Impaired renal function and haemodialysis | As in 1.2 above; on dialysis days after dialysis. |
| 2. Impaired renal function and CAPD | |
| 2.1 Oral administration of either ciprofloxacin film coated 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 4 times a day. | |
| 3. Liver function disturbances: | No dose adjustment. |
| 4. Liver and kidney insufficiency: | As in 1.1 and 1.2 above. |

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

The following side-effects have been observed:

Effects on the gastrointestinal tract:

Nausea, diarrhoea, vomiting, dyspepsia, abdominal pain, flatulence, anorexia. In the event of severe and persistent diarrhoea during or after treatment, a doctor must be consulted since this symptom can hide a serious intestinal disease (pseudomembranous colitis), requiring immediate treatment. In such cases ciprofloxacin must be discontinued and appropriate therapy initiated (e.g. vancomycin, orally, 4 x 250 mg/day). Drugs that inhibit peristalsis are contra-indicated.

Effects on the nervous system:

Dizziness, headache, tiredness, nervousness, agitation, trembling. Infrequently: insomnia, peripheral paralgia, sweating, unsteady gait, convulsions, increase in intracranial pressure, anxiety states, nightmares, confusion, depression, hallucinations, in individual cases psychotic reactions (even progressing to self endangering behaviour).

In some instances, these reactions occurred already after the first administration of ciprofloxacin. In these cases ciprofloxacin has to be discontinued and the doctor should be informed immediately.

Reactions on sensory organs:

Impaired taste and smell, visual disturbances (e.g. diplopia, colour vision), tinnitus, transitory impairment of hearing, especially at high frequencies.

Hypersensitivity reactions:

Skin reactions, e.g. rashes, pruritus, drug fever.

Infrequently: punctate skin haemorrhages (petechiae), blister formation with accompanying haemorrhages (haemorrhagic bullae) and small nodules (papules) with crust formation showing vascular involvement (vasculitis). Erythema nodosum, erythema exsudativum multiforme (minor), Stevens-Johnson Syndrome, Lyell Syndrome. Interstitial nephritis, hepatitis, hepatic necrosis very seldom progressing to life-threatening hepatic failure. Anaphylactic/anaphylactoid reactions (e.g. facial, vascular and laryngeal oedema, dyspnoea progressing to life-threatening shock), in some instances after the first administration. In these cases ciprofloxacin has to be discontinued and medical treatment (e.g. treatment for shock) is required.

Effects on the cardiovascular system:

Tachycardia, hot flushes, migraine, fainting.

Other side effects:

Joint pain, joint swelling. Very rarely: general feeling of weakness, muscular pains, tendosynovitis, photosensitivity, transient impairment in kidney function including transient kidney failure.

In single cases during the administration of ciprofloxacin, achillotendinitis was observed. Cases of partial or complete rupture of the achilles tendon have been reported predominantly in the elderly on prior systemic treatment with glucocorticoids. Therefore, at any signs of an achillotendinitis (e.g. painful swelling) the administration of ciprofloxacin should be discontinued and a physician be consulted. Long-term or repeated administration of ciprofloxacin can lead to superinfections with resistant bacteria or yeast-like fungi.

Effects on the blood and blood constituents:

Eosinophilia, leucocytopenia, granulocytopenia, anaemia, thrombocytopenia. Very rarely: leucocytosis, thrombocytosis, haemolytic anaemia, altered prothrombin values.

Influence on laboratory parameters/urinary sediment:

There can be a temporary increase in transaminases, alkaline phosphatase or cholestatic jaundice, especially in patients with previous liver damage, temporary increase in urea, creatinine or bilirubin in the serum; in individual cases: hyperglycaemia, crystalluria or haematuria.

Other Information:

Even when the medicine is taken as prescribed, it can affect the speed of reaction to such an extent that the ability to drive or to operate machinery is impaired. This applies particularly in combination with alcohol.

Interactions:

Concurrent administration of DYNAFLOC 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 adverse reactions. If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate. DYNAFLOC 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 nonsteroidal anti-inflammatory drug fenbufen with quinolones has been reported to increase the risk of central nervous system stimulation and convulsive seizures. Monitoring of serum creatinine concentrations is advised in patients on concomitant ciclosporin therapy, as transient increases in serum creatinine concentrations have been observed. The simultaneous administration of DYNAFLOC and warfarin may intensify the action of warfarin.

In particular cases, concurrent administration of DYNAFLOC and glibenclamide can intensify the action of glibenclamide (hypoglycaemia). Probenecid interferes with renal secretion of DYNAFLOC. Co-administration of probenecid and DYNAFLOC increases the DYNAFLOC serum concentrations. Metoclopramide accelerates the absorption of DYNAFLOC, resulting in a shorter time to reach maximum plasma concentrations. No effect was seen on the bioavailability of DYNAFLOC.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of acute, excessive oral overdosage, reversible renal toxicity has been reported. Therefore, apart from routine emergency measures, it is recommended to monitor renal function and to administer Mg- or Ca-containing antacids which reduce the absorption of ciprofloxacin. Only a small amount of ciprofloxacin (< 10%) is removed from the body after haemodialysis or peritoneal dialysis.

Treatment is symptomatic and supportive.

IDENTIFICATION:

DYNAFLOC 250: White or yellowish, 11 mm round, biconvex, film-coated tablets, scored on one side.
DYNAFLOC 500: White or yellowish, 18 x 8 mm oblong, biconvex, film-coated tablets, scored on one side.

PRESENTATION:

Blister packs of 10 and 100 tablets.

STORAGE INSTRUCTIONS:

Store in a cool (below 25°C), dry place. Protect from light. Do not remove tablets from the outer carton until required for use.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBERS:

DYNAFLOC 250: 34/20.1.1/0404
DYNAFLOC 500: 34/20.1.1/0405

NAME AND BUSINESS ADDRESS OF APPLICANT:

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WESTLAKE

7945

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

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DYNAFLOC 250 DYNAFLOC 500

SKEDULERINGSSTATUS:

S4

EIENDOMSNAAM (EN DOSEERVORM):

DYNAFLOC 250 (tablette)

DYNAFLOC 500 (tablette)

SAMESTELLING:

Elke DYNAFLOC 250 tablet bevat siprofloksasienhydrochloriedmonohidraat, ekwivalent aan 250 mg siprofloksasien.

Elke DYNAFLOC 500 tablet bevat siprofloksasienhydrochloriedmonohidraat, ekwivalent aan 500 mg siprofloksasien.

FARMAKOLOGIESE KLASSIFIKASIE:

A: 20.1.1. Breë-en mediumspektrumantibiotika.

FARMAKOLOGIESE WERKING:

Siprofloksasien is 'n sintetiese, 4-kinoloon-derivaat wat oor *in vitro* bakteriedodende werking teen die volgende Gram-negatiewe en Gram-positiewe organismes beskik. *In vitro* sensitiwiteit impliseer nie noodwendig *in vivo* doeltreffendheid nie.

<i>Acinetobacter</i>	<i>Haemophilus influenzae</i>	<i>Proteus vulgaris</i>	<i>Streptococcus</i>
<i>Aeromonas</i>	<i>Haemophilus para-influenzae</i>	<i>Providencia rettgeri</i>	<i>pyogenes</i>
<i>Brucella</i>	<i>Hafnia</i>	<i>Providencia stuartii</i>	<i>Streptococcus species</i>
<i>Campylobacter jejuni</i>	<i>Klebsiella species</i>	<i>Pseudomonas</i>	<i>Streptococci viridans</i>
<i>Citrobacter freundii</i>	<i>Listeria</i>	<i>aeruginosa</i>	<i>Vibrio</i>
<i>Citrobacter species</i>	<i>Moraxella catarrhalis</i>	<i>Salmonella enteritidis</i>	<i>Yersinia</i>
<i>Corynebacterium</i>	<i>Morganella morganii</i>	<i>Serratia marcescens</i>	
<i>E. coli</i>	<i>Neisseria gonorrhoea</i>	<i>Shigella flexneri</i>	
<i>Edwardsiella</i>	<i>Pasteurella</i>	<i>Shigella sonnei</i>	
<i>Enterobacter cloacae</i>	<i>Plesiomonas</i>	<i>Staphylococcus aureus</i>	
<i>Enterobacter species</i>	<i>Proteus mirabilis</i>	<i>Staphylococcus</i>	
		<i>epidermidis</i>	
		<i>Streptococcus faecalis</i>	

Die volgende organismes toon wisselende grade van *in vitro* sensitiwiteit teenoor siprofloksasien:

Alcaligenes, *Enterococcus faecalis*, *Flavobacterium*, *Gardnerella*, *Legionella*, *Mycobacterium fortuitum*, *Mycobacterium tuberculosis*, *Mycoplasma hominis*, *Streptococcus agalactiae*, *Chlamydia*.

Die volgende is gewoonlik weerstandig:

Enterococcus faecium, *Ureaplasma urealyticum*, *Nocardia asteroides*. Behalwe vir 'n paar uitsonderings is anaërobe matig sensitief (bv. *Peptococcus*, *Peptostreptococcus*) tot weerstandig (bv. *Bacteriodes*, *Treponema pallidum*).

Siprofloksasien plasmavlakke is dosisverwant en bereik 'n piek 0,5 – 2 uur na inname. Die absolute orale biobesikbaarheid is ongeveer 70% met geen noemenswaardige verlies deur eerste verbygangmetabolisme nie. Siprofloksasien word wyd versprei en die volume van distribusie is hoog wat dui op omvattende binnedringing van die weefsels. Siprofloksasien kom in die long, vel, vet, spiere, kraakbeen en been voor. Dit kom ook in aktiewe vorm in die speeksel, nasale en brongiale afskeidings, sputum, vesikale vog van die vel, limf, peritoneale vog, galsekresies, prostatiese sekresies, serebrospinale vog en die voorkamervog voor. Proteïenbinding is laag. Nadat 'n dosis oraal toegedien is, word 40 tot 50% daarvan in die urien as onveranderde geneesmiddel uitgeskei. Ongeveer 15% van 'n enkel dosis siprofloksasien word as metaboliëte uitgeskei. Uitskeiding geskied hoofsaaklik deur die niere en veral gedurende die eerste 12 uur na inname. Renale opruiming is ongeveer 300 ml/minuut. Die uitskeidingshalflewe van onveranderde siprofloksasien is 3 – 5 uur. Die uitskeidingskinetika is lineêr; na herhaalde doserings met 12-uurlikse tussenpose en nadat die distribusie-ewewig bereik is, word geen verdere ophoping gevind nie.

INDIKASIES:

DYNAFLOC word aangedui vir die behandeling van die volgende infeksies wat deur sensitiewe bakterieë veroorsaak word:

Onderste Lugweginfeksies veroorsaak deur *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Haemophilus influenzae* en *Haemophilus parainfluenzae*.

Urienweginfeksies veroorsaak deur *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Serratia marcescens*, *Proteus mirabilis*, *Providencia rettgeri*, *Morganella morganii*, *Citrobacter diversus*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus epidermidis* en *Streptococcus faecalis*.

Vel- en sagte weefselinfeksies veroorsaak deur *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Proteus mirabilis*, *Proteus vulgaris*, *Providencia stuartii*, *Morganella morganii*, *Citrobacter freundii*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Staphylococcus epidermidis* en *Streptococcus pyogenes*.

Gastro-intestinale infeksies: Infektiewe diarree veroorsaak deur *E. coli*, *Campylobacter jejuni*, *Shigella flexneri* en *Shigella sonnei*.

Beeninfeksies: Osteïemielitis as gevolg van vatbare Gram-negatiewe organismes.

Gonorree.

DYNAFLOC is oneffektief teenoor *Treponema pallidum*.

In die behandeling van infeksies wat deur *Pseudomonas aeruginosa* veroorsaak word, moet 'n aminoglikosied gelyktydig toegedien word.

KONTRA-INDIKASIES:

Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

DYNAFLOC is teenaangedui in kinders jonger as 18 jaar en by groeiende adolessente, behalwe waar die voordele van behandeling die risiko oorskry. Eksperimentele gegewens toon dat, spesie-veranderlike, omkeerbare letsels van die kraakbeen van gewigsdraende gewigte by onvolwasse lede van sekere diersoorte waargeneem is.

DYNAFLOC word teenaangedui by pasiënte wat 'n hipersensitiwiteit vir siprofloksasien of ander kinolone vertoon het.

WAARSKUWINGS:

DYNAFLOC moet met omsigtigheid gebruik word by pasiënte met 'n geskiedenis van konvulsiewe toestande.

Kristalurie geassosieerd met die gebruik van DYNAFLOC is waargeneem. Pasiënte wat DYNAFLOC ontvang moet 'n goeie hidrasie handhaaf en oormatige alkaliniteit van die urien moet vermy word.

DOSIS EN GEBRUIKSAANWYSINGS:

DYNAFLOC tablette moet heel ingesluk word tesame met baie vloeistof en kan met of sonder etes geneem word.

Dosisgradering en Behandelingsduur:

Die dosisgrense is 250 – 750 mg twee maal per dag. Die duur van behandeling hang af van die graad van erns van die infeksie, kliniese reaksie en bakteriologiese bevindinge. Vir akute, ongekompliseerde sistitis in vroue, is die behandelingsperiode 3 dae. Gewoonlik moet daar met behandeling vir ten minste 3 dae voortgegaan word nadat die tekens en simptome van die infeksie opgeklaar het. Vir akute infeksies is die normale tydperk van behandeling met DYNAFLOC tablette 5 – 10 dae. Vir ernstige en gekompliseerde infeksies kan 'n langer behandelingsduur nodig wees. In streptokokkale infeksies moet behandeling ten minste 10 dae duur as gevolg van die risiko van nasleepkomplikasies.

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

Urienweginfeksie: Akute, ongekompliseerde sistitis – 250 mg twee maal daaglik; 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 van 4 – 6 weke of langer mag nodig wees.

Gonorrée: 'n Enkel dosis van 250 mg.

Bejaarde pasiënte moet die laagste moontlike dosis ontvang; dit sal deur die erns van die siekte en die kreatinienopruiming bepaal word.

Ingekorte nier- óf lewerfunksie:

By pasiënte met ingekorte nierfunksie word die halflewe van siprofloksasien verleng en die dosis moet aangepas word.

By pasiënte met veranderende nierfunksie of pasiënte met ingekorte nierfunksie en lewerfunksieontoereikendheid, sal die bloedvlakbepaling van die geneesmiddel die betroubaarste indeks vir dosisaanpassings wees.

Dosisaanpassing van siprofloksasien by pasiënte met nier- en/of lewerinkorting.

1. Nierontoereikendheid:	
1.1 $CL_{Cr} \geq 31 \text{ ml/min/1,73 m}^2 \leq 60 \text{ ml/min/1,73 m}^2$	Maks 1000 mg/dag per mond.
1.2 $CL_{Cr} \leq 30 \text{ ml/min/1,73 m}^2$	Maks 500 mg/dag per mond.
1.3 Ingekorte nierfunksie en hemodialise	Soos 1.2 hierbo; op dialise dae na dialise.
2. Ingekorte nierfunksie en KAPD	
2.1 Orale toediening van siprofloksasien filmbedekte tablet as 500 mg tablet of 2 x 250 mg tablette is aangedui.	
2.2 Vir KAPD pasiënte met peritonitis, is die aanbevole daaglikse orale dosis 500 mg 4 keer per dag.	
3. Lewerfunksie versteurings:	Geen dosisaanpassing nodig nie.
4. Lewer- en nierinkorting:	Soos in 1.1 en 1.2 hierbo.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Die volgende newe-effekte is opgemerk:

Newe-effekte m.b.t. die spysverteringskanaal:

Naarheid, diarree, braking, dispepsie, abdominale pyn, winderigheid, anoreksie. Mits ernstige en aanhoudende diarree tydens of na behandeling voorkom, moet 'n geneesheer geraadpleeg word, omdat hierdie simptome 'n ernstige ingewand siekte (pseudomembraneuse kolitis) wat onmiddellike behandeling verg, kan verberg. In sulke gevalle moet siprofloksasien gestaak word en toepaslike terapie begin word (bv. vankomisien, mondelings, 4 x 250 mg/dag). Geneesmiddels wat peristalse inhibeer, is teenaangedui.

Newe-effekte m.b.t. die sentrale senuweestelsel (SSS);

Duiseligheid, hoofpyn, moegheid, senuagtigheid, rusteloosheid, bewing. Selde: slaaploosheid, perifere paralgiesie, sweet, wankelende gang, stuipe, toename in intrakraniale druk, angstoestande, nagmerries, verwardheid, depressie, hallusinasies, en in individuele gevalle is psigotiese reaksies (wat selfs tot gedrag wat die persoon in gevaar stel, kan ontwikkel) waargeneem.

In sommige gevalle het hierdie reaksies alreeds na die eerste toediening van siprofloksasien plaasgevind. In sulke gevalle moet siprofloksasien gestaak word en die geneesheer moet onmiddelik ingelig word.

Reaksies van die sensoriese organe:

Belemmerde smaak en reuk, versteurde visie (bv. diplopie, kleurwaarneming), tinnitus, verbygaande gehoorversteuring, veral teen hoë frekwensies.

Hipersensitiwiteitsreaksies:

Velreaksies, bv. veluitslae, pruritus, medikamentkoors.

Selde: punktaat velbloedings (petegia), blaasvorming met meegaande bloeding (hemorragiese bulle) en klein nodules (papulae) met korsvorming met vaskulêre betrokkenheid (vaskulitis). Erythema nodosum, erythema exsudativum multiforme (minor), Stevens-Johnson se sindroom, Lyell se sindroom. Interstisiële nefritis, hepatitis, lewernekrose wat baie selde tot lewensgevaarlike lewersaking lei. Anafilaktiese/anafilatoïede reaksies (bv. gesigs, vaskulêre en laringale edeem, dispnee wat ontwikkel tot lewensgevaarlike skok), in sommige gevalle alreeds na die eerste toediening. In sulke gevalle moet siprofloksasien gestaak word en mediese behandeling (b.v. behandeling vir skok), gegee word.

Neuwe-effekte m.b.t. die kardiiovaskulêre sisteem:

Tagikardie, gloede, migraine, floutes.

Ander neue-effekte:

Gewrigspyn en –swelling. Baie selde: algemene swakheidsgevoelens, spierpyne, tendosinovitis, fotosensitiwiteit, verbygaande nierfunksie inkorting, insluitende verbygaande nierversaking.

In enkele gevalle is achillotendinitis tydens toediening van siprofloksasien waargeneem. Gevalle van gedeeltelike of algehele skeuring van die achillespees is veral in bejaardes wat vooraf behandeling met glukokortikosteroïde ontvang, gerapporteer. Gevolglik moet die toediening van siprofloksasien gestaak word as daar enige tekens van achillotendinitis (bv. pynlike swelling) voorkom en 'n geneesheer moet geraadpleeg word. Langtermyn of herhaalde toediening van siprofloksasien kan tot superinfeksies met weerstandbiedende bakterieë of gisagtige swamme lei.

Neuwe-effekte m.b.t. bloed en bloedbestanddele:

Eosinofilie, leukositopenie, granulositopenie, anemie, trombositopenie. Baie selde: leukositose, trombositose, hemolitiese anemie, veranderde protrombienwaardes.

Invloed op laboratorium uitslae/urinêre sediment:

'n Tydelike verhoging in transaminases, alkaliese fosfatase of cholestatiëse geelsug veral in pasiënte met voorafgaande lewerskade kan voorkom, tydelike toename in ureum, kreatinien of bilirubien in die serum; in individuele gevalle: hiperglisemie, kristallurie of hematurie.

Ander inligting:

Selfs in gevalle waar die medisyne volgens voorskrif geneem word, kan dit reaksiespoed tot so 'n mate vertraag dat die vermoë om te bestuur of om masjinerie te hanteer, belemmer word. Dit is veral van toepassing wanneer die middel saam met alkohol gebruik word.

Interaksies:

Gelyktydige toediening van DYNAFLOC met teofillien kan tot verhoogde plasmavlakke van teofillien en verlenging van die elimineringshalflewe lei. Dit kan lei tot 'n verhoogde risiko in teofillienverwante neueffekte. Indien gelyktydige gebruik nie vermy kan word nie, moet plasmavlakke van teofillien gemonitor word

en soos nodig moet dosisaanpassings gemaak word.

DYNAFLOC tablette moet ten minste 1–2 uur voor of ten minste 4 uur nadat ysterpreparate, magnesium-, aluminium-, kalsium- of sukralfaatbevattende teensuur-middels geneem is, toegedien word aangesien dit die absorpsie daarvan mag beïnvloed. Hierdie beperking is nie van toepassing op teensuurmiddels wat aan die H₂ reseptorblokkeerderklas behoort nie.

Gelyktydige toediening van die nie-steroïedale anti-inflammatoriese middel, fenbufen met kinolone kan die risiko van sentrale senuweestelsel-stimulasie en konvulsiewe aanvalle verhoog. Gereelde bepaling van serumkreatinienvlakke word aanbeveel vir pasiënte wat ook met siklosporiene behandel word, waar verbygaande stygings van serumkreatinien waargeneem is. Die gelyktydige toediening van DYNAFLOC en warfarien mag die werking van warfarien versterk. In uitsonderlike gevalle mag die gelyktydige toediening van DYNAFLOC en glibenklamied die werking van glibenklamied versterk (hipoglisemie).

Probenesied versteur die renale uitskeiding van DYNAFLOC. Gelyktydige toediening van probenesied en DYNAFLOC verhoog die serumkonsentrasie van DYNAFLOC.

Metoklopramied versnel die absorpsie van DYNAFLOC, wat veroorsaak dat maksimum plasmavlakke vinniger bereik word. Geen uitwerking op die biobesikbaarheid van DYNAFLOC is waargeneem nie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

In gevalle van akute, oormatige orale oordosering, is omkeerbare niertoksisiteit gerapporteer. Gevolglik is dit raadsaam om benewens roetine noodbehandeling, ook nierfunksie te monitor en om Mg- of Ca-bevattende teensuurmiddels wat die absorpsie van siprofloksasien verminder, toe te dien. Slegs 'n klein hoeveelheid siprofloksasien (< 10%) word van die liggaam na hemodialise of peritoneale dialise verwyder. Behandeling is simptome en ondersteunend.

IDENTIFIKASIE:

DYNAFLOC 250: 'n Wit tot geel, 11 mm ronde, bikonvekse, filmbedekte tablet, gekeep aan een kant.

DYNAFLOC 500: Wit tot geel, 18 x 8 mm langwerpige, bikonvekse, filmbedekte tablet, gekeep aan een kant.

AANBIEDING:

Stulpverpakkings met 10 en 100 tablette.

BERGINGSINSTRUKSIES:

Bewaar op 'n koel (benede 25°C), droë plek. Beskerm teen lig. Moenie die tablette uit die kartondoos verwyder tot voor gebruik nie.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS:

DYNAFLOC 250: 34/20.1.1/0404

DYNAFLOC 500: 34/20.1.1/0405

NAAM EN BESIGHEIDSADRES VAN APPLIKANT:

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