Bosch

For Medical Professional only

Quinoflox® Tablets
(Ciprofloxacin)

کوئینوفلوکس ٹیبلیٹس
(سپروفلاکساسن)

DESCRIPTION:
Ciprofloxacin hydrochloride, USP, a fluoroquinolone, is the monohydrochloride monohydrate salt of 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3¬ quinolinecarboxylic acid. It is a faintly yellowish to light yellow crystalline substance with a molecular weight of 385.8. Its empirical formula is $C_{17}H_{18}FN_3O_3$•HCl•H_2O. Ciprofloxacin is 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7- (1-piperazinyl)-3-quinolinecarboxylic acid. Its empirical formula is $C_{17}H_{18}FN_3O_3$ and its molecular weight is 331.4.

COMPOSITION:
Quinoflox 100mg Tablets:
Each film coated tablet contains:
Ciprofloxacin.....100mg as Ciprofloxacin HCl U.S.P.
(Product Specs.: U.S.P.)

Quinoflox 250mg Tablets:
Each film coated tablet contains:
Ciprofloxacin.....250mg as Ciprofloxacin HCl U.S.P.
(Product Specs.: U.S.P.)

Quinoflox 500mg Tablets:
Each film coated tablet contains:
Ciprofloxacin.....500mg as Ciprofloxacin HCl U.S.P.
(Product Specs.: U.S.P.)

Quinoflox 750mg Tablets:
Each film coated tablet contains:
Ciprofloxacin.....750mg as Ciprofloxacin HCl U.S.P.
(Product Specs.: U.S.P.)

CLINICAL PHARMACOLOGY:
Pharmacodynamic Properties:
Pharmacotherapeutic Group: Fluoroquinolones ATC code: J01MA02

Mechanism of Action:
As a fluoroquinolone antibacterial agent, the bactericidal action of ciprofloxacin results from the inhibition of both type II topoisomerase (DNA-gyrase) and topoisomerase IV, required for bacterial DNA replication, transcription, repair and recombination.

Microbiology:
Gram-Positive Bacteria:
- Bacillus anthracis
- Enterococcus faecalis
- Staphylococcus spp.
- Actinomyces
- Enteroccus faecium
- Listeria monocytogenes

Gram-Negative Bacteria:
- Aeromonas spp
- Brucella spp.
- Citrobacter koseri
- Francisella tularensis
- Haemophilus ducreyi
- Haemophilus influenzae
- Legionella spp.
- Moraxella catarrhalis
- Neisseria meningitidis
- Pasteurella spp.
- Salmonella spp.
- Shigella spp
- Vibrio spp.
- Yersinia pestis
- Acinetobacter baumannii
- Burkholderia cepacia
- Campylobacter spp.
- Citrobacter freundii
- Enterobacter aerogenes
- Enterobacter cloacae
- Escherichia coli
- Klebsiella oxytoca
- Klebsiella pneumoniae
- Morganella morganii
- Neisseria gonorrhoeae
- Proteus mirabilis
- Proteus vulgaris
- Providencia spp.
- Pseudomonas aeruginosa
- Pseudomonas fluorescens
- Serratia marcescens
- Stenotrophomonas maltophilia

Anaerobic Bacteria:
- Mobiluncus
- Peptostreptococcus spp.
- Propionibacterium acnes

Other:
- Chlamydia trachomatis
- Chlamydia pneumoniae
- Mycoplasma hominis
- Mycoplasma pneumoniae
- Mycoplasma genitalium
- Ureaplasma urealitycum

THERAPEUTIC INDICATIONS:
Adults
- Lower respiratory tract infections
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram negative bacteria
- Urinary tract infections
- Genital tract infections
- Infections of the gastro-intestinal tract
- Intra-abdominal infections
- Infections of the skin and soft tissue caused by Gram-negative bacteria
- Malignant external otitis
- Infections of the bones and joints
- Prophylaxis of invasive infections due to Neisseria meningitides
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

Ciprofloxacin may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Children and adolescents:
- Broncho-pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis
- Complicated urinary tract infections and pyelonephritis
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)

DOSAGE AND ADMINISTRATION:
Adults:

Indications		**Daily dose in mg**
Infections of the lower respiratory tract		500mg twice to 750mg twice daily
Infections of the upper respiratory tract	Acute exacerbation of chronic sinusitis	500mg twice to 750mg twice daily
	Chronic suppurative otitis media	500mg twice to 750mg twice daily
	Malignant external otitis	750mg twicedaily
Urinary tract infections	Uncomplicated acute cystitis	250mg twice to 500mg twice daily
	Complicated cystitis, Acute pyelonephritis	500mg twice daily
	Complicated pyelonephritis	500mg twice daily to 750mg twice daily
	Bacterial Prostatitis	500mg twice daily to 750mg twice daily
Genital tract infections	Gonococcal urethritis and cervicitis	500mg as a single dose
	Epididymo - orchitis and pelvic infammatory diseases	500mg twice to 750mg twice daily
Infections of the gastro-intestinal tract and intra-abdominal infections	Diarrhoea	500mg twice daily
	Typhoid fever	500mg twice daily
	Intra - abdominal infections	500mg twice to 750mg twice daily
Infections of the skin and soft tissue		500mg twice to 750mg twice daily
Bone and joint infections		500mg twice to 750mg twice daily
Neutropenic patients with fever that is suspected to be due to a bacterial infection.		500mg twice to 750mg twice daily
Prophylaxis of invasive infections		500mg as a single dose
Inhalation anthrax post-exposure prophylaxis		500mg twice daily

Drug administration should begin as soon as possible after suspected or confirmed exposure.

Paediatric population:

Indications	Daily dose in mg
Cystic fibrosis	20mg/kg body weight twice daily with a maximum of 750mg per dose
Complicated urinary tract infections and pyelonephritis	10mg/kg body weight twice daily to 20mg/kg body weight twice daily with a maximum of 750mg per dose
Inhalation anthraxpost-exposure prophylaxis and curative treatment	10mg/kg body weight twice daily to15mg/kg body weight twice daily with a maximum of 500mg per dose
Other severe infections	20mg/kg body weight twice daily with a maximum of 750mg per dose

Elderly patients
Elderly patients should receive a dose selected according to the severity of the infection and the patient's creatinine clearance.

Patients with Renal and hepatic impairment
Recommended starting and maintenance doses for patients with impaired renal function:

Creatinine Clearance [mL/min/1.73 m^2]	**Serum Creatinine [µmol/L]**	**Oral Dose [mg]**
>60	<124	See Usual Dosage
30-60	124 to 168	250-500mg every 12 h
<30	>169	250-500mg every 24 h
Patients on haemodialysis	>169	250-500mg every 24 h (after dialysis)
Patients on peritoneal dialysis	>169	250-500mg every 24 h

Method of Administration:
Tablets are to be swallowed unchewed with fluid. They can be taken independent of mealtimes. If taken on an empty stomach, the active substance is absorbed more rapidly. Ciprofloxacin tablets should not be taken with dairy products (e.g. Milk, yoghurt) or mineral-fortified fruit juice (e.g. calcium-fortified orange juice).

CONTRAINDICATIONS:
Hypersensitivity to the active substance, to other quinolones or to any of the excipients.

WARNINGS AND PRECAUTIONS:
Severe infections and mixed infections
Ciprofloxacin monotherapy is not suited for treatment of severe infections and infections that might be due to Gram-positive or anaerobic pathogens. In such infections Ciprofloxacin must be co-administered with other appropriate antibacterial agents.

Streptococcal Infections
Ciprofloxacin is not recommended for the treatment of streptococcal infections due to inadequate efficacy.

Genital tract infections
Ciprofloxacin should be administered for the treatment of gonococcal uretritis or cervicitis only if ciprofloxacin-resistant Neisseria gonorrhoeae can be excluded.
For epididymo-orchitis and pelvic inflammatory diseases, empirical ciprofloxacin should only be considered in combination with another appropriate antibacterial agent. If clinical improvement is not achieved after 3 days of treatment, the therapy should be reconsidered.

Urinary tract infections
The single dose of ciprofloxacin that may be used in uncomplicated cystitis in pre-menopausal women is expected to be associated with lower efficacy than with the longer treatment duration. This is to be taken into account as regards the increasing resistance level of Escherichia coli to quinolones.

Intra-abdominal infections
There are limited data on the efficacy of ciprofloxacin in the treatment of post-surgical intra-abdominal infections.

Infections of the bones and joints
Ciprofloxacin should be used in combination with other antimicrobial agents depending on the results of the microbiological documentation.

Tendinitis and tendon rupture
Ciprofloxacin should generally not be used in patients with a history of tendon disease/disorder related to quinolone treatment.

Patients with myasthenia gravis
Ciprofloxacin should be used with caution in patients with myasthenia gravis, because symptoms can be exacerbated.

Vision disorders
If vision becomes impaired or any effects on the eyes are experienced, an eye specialist should be consulted immediately.

Photosensitivity
Ciprofloxacin has been shown to cause photosensitivity reactions. Patients taking ciprofloxacin should be advised to avoid direct exposure to either extensive sunlight or UV irradiation during treatment.

Seizures
Ciprofloxacin like other quinolones are known to trigger seizures or lower the seizure threshold. Cases of status epilepticus have been reported.

Peripheral neuropathy
Cases of sensory or sensorimotor polyneuropathy resulting in paraesthesia, hypaesthesia, dysesthesia, or weakness have been reported in patients receiving quinolones and fluoroquinolones.

Dysglycemia
As with all quinolones, disturbances in blood glucose, including both hypoglycaemia and hyperglycaemia have been reported.

Gastrointestinal System
The occurrence of severe and persistent diarrhoea during or after treatment (including several weeks after treatment) may indicate an antibiotic-associated colitis.

Renal and urinary system
Crystalluria related to the use of ciprofloxacin has been reported.

Glucose-6-phosphate dehydrogenase deficiency
Haemolytic reactions have been reported with ciprofloxacin in patients with glucose-6-phosphate dehydrogenase deficiency.

Cytochrome P450
Ciprofloxacin inhibits CYP1A2 and thus may cause increased serum concentration of concomitantly administered substances metabolised by this enzyme.

Methotrexate
The concomitant use of ciprofloxacin with methotrexate is not recommended.

DRUG INTERACTIONS:
Drugs known to prolong QT interval
Ciprofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong QT interval.

Chelation Complex Formation
The simultaneous administration of ciprofloxacin (oral) and multivalent cation-containing drugs and mineral supplements, polymeric phosphate binders, sucralfate or antacids, and highly buffered drugs reduces the absorption of ciprofloxacin. Consequently, ciprofloxacin should be administered either 1-2 hours before or at least 4 hours after these preparations. The restriction does not apply to antacids belonging to the class of H2 receptor blockers.

Probenecid
Probenecid interferes with renal secretion of ciprofloxacin. Co-administration of probenecid and ciprofloxacin increases ciprofloxacin serum concentrations.

Metoclopramide
Metoclopramide accelerates the absorption of ciprofloxacin (oral) resulting in a shorter time to reach maximum plasma concentrations.

Omeprazole
Concomitant administration of ciprofloxacin and omeprazole containing medicinal products results in a slight reduction of Cmax and AUC of ciprofloxacin.

Theophylline
Concurrent administration of ciprofloxacin and theophylline can cause an undesirable increase in serum theophylline concentration. This can lead to theophylline-induced side effects.

Other xanthine derivatives
On concurrent administration of ciprofloxacin and caffeine or pentoxifylline (oxpentifylline), raised serum concentrations of these xanthine derivatives were reported.

Phenytoin
Simultaneous administration of ciprofloxacin and phenytoin may result in increased or reduced serum levels of phenytoin such that monitoring of drug levels is recommended.

Cyclosporin
A transient rise in the concentration of serum creatinine was observed when ciprofloxacin and cyclosporin containing medicinal products were administered simultaneously.

Vitamin K antagonists
Simultaneous administration of ciprofloxacin with a vitamin K antagonist may augment its anti-coagulant effects.

Zolpidem
Co-administration ciprofloxacin may increase blood levels of zolpidem, concurrent use is not recommended.

ADVERSE EFFECTS:
Common:
Nausea, Diarrhoea.

Uncommon:
Mycotic, super infections, Eosinophilia, Vomiting, Gastrointestinal and abdominal pain.

Rare:
Leukopenia, Anaemia, Neutropenia, Leukocytosis, Thrombocytopenia, Thrombocythemia, Allergic reaction, Allergic oedema/ angioedema, Decreased appetite, Psychomotor hyperactivity / agitation, Confusion and disorientation, Anxiety reaction, Abnormal dreams, Depression (potentially culminating in suicidal ideations/ thoughts or suicide attempts and completed suicide), Hallucinations, Par- and Dysaesthesia, Hypoaesthesia, Tremor, Seizures, Vertigo, Visual disturbances (e.g. diplopia), Tinnitus, Hearing loss/ Hearing impaired, Tachycardia, Vasodilatation, Hypotension, Syncope, Dyspnoea (including asthmatic condition), Antibiotic associated colitis (very rarely with possible fatal outcome.

Very Rare:
Haemolytic anaemia, Agranulocytosis, Pancytopenia, Bone marrow depression,

Anaphylactic reaction, Anaphylactic shock, Serum sickness-like reaction, Psychotic reactions (potentially culminating in suicidal ideations/ thoughts or suicide attempts and completed suicide), Migraine, Disturbed coordination, Gait disturbance, Olfactory nerve disorders, Intracranial hypertension and pseudotumor cerebri, Visual colour distortions, Vasculitis, Pancreatitis.

Not Known:
Syndrome of inappropriate secretion of antidiuretic hormone (SIADH), Hypoglycaemic coma, Mania, incl. Hypomania, Peripheral neuropathy and poly neuropathy, Ventricular arrhythmia and torsades de pointes (reported predominantly in patients with risk factors for QT prolongation), ECG QT prolonged.

USE IN PREGNANCY AND LACTATION:
Pregnancy:
As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy.

Lactation:
Ciprofloxacin is excreted in breast milk. Due to the potential risk of articular damage, ciprofloxacin should not be used during breast-feeding.

OVERDOSE:
An overdose of 12g has been reported to lead to mild symptoms of toxicity. An acute overdose of 16g has been reported to cause acute renal failure. In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

SHELF LIFE:
3 years

STORAGE:
Protect from heat, sunlight & moisture, store between 15°C-30°C.
The expiration date refer to the product correctly stored at the required condition.
Keep out of the reach of children
Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com.
To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
Quinoflox Tablets 100mg: Cold Form & Cold Seal blister pack of 10 film coated tablets.
Quinoflox Tablets 250mg: Cold Form & Cold Seal blister pack of 10 film coated tablets.
Quinoflox Tablets 500mg: Cold Form & Cold Seal blister pack of 10 film coated tablets.
Quinoflox Tablets 750mg: Cold Form & Cold Seal blister pack of 10 film coated tablets.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔ بچّوں کی پہنچ سے دُور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

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