Quinoflox® INFUSION

(Ciprofloxacin)

100mg/50mL, 200mg/100mL & 400mg/100mL DS

کوئینوفلوکس انفیوژن

(سپروفلاکساسن)

WARNING: Serious Adverse Reactions Including Tendinitis Tendon Rupture Peripheral Neuropathy, Central Nervous System Effects & exacerbation of Myasthenia Gravis

Fluoroquinolones, including Ciprofloxacin, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including:

- Tendinitis and tendon rupture
- Peripheral neuropathy, Central nervous system effects

Discontinue Ciprofloxacin immediately and avoid the use of fluoroquinolones, including Ciprofloxacin, in patients who experience any of these serious adverse reactions. Fluoroquinolones, including Ciprofloxacin, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Ciprofloxacin in patients with known history of myasthenia gravis.

Because fluoroquinolones, including Ciprofloxacin, have been associated with serious adverse reactions, reserve Ciprofloxacin for use in patients who have no alternative treatment options for the following indications:

- Acute exacerbation of chronic bronchitis
- Acute uncomplicated cystitis (not for Ciprofloxacin injection)
- Acute sinusitis

QUALITATIVE AND QUANTITATIVE COMPOSITION

Quinoflox 100mg/50mL Infusion

Each 50mL vial contains:
Ciprofloxacin Lactate eq. to
Ciprofloxacin USP.....100mg
Sodium Chloride USP.....450mg
(Product specs: USP)

Quinoflox 200mg/100mL Infusion

Each 100mL vial contains:
Ciprofloxacin Lactate eq. to
Ciprofloxacin USP.....200mg
Sodium Chloride USP.....900mg
(Product Specs: USP)

Quinoflox DS 400mg/100mL Infusion

Each 100mL vial contains:
Ciprofloxacin Lactate eq. to
Ciprofloxacin USP.....400mg
Sodium Chloride USP.....900mg
(Product Specs: USP)

PHARMACEUTICAL FORM

Solution for Infusion

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS:

Quinoflox Infusion is indicated for the treatment of the following.

Adults

- Lower respiratory tract infections due to gram-negative bacteria;
- Broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
- Pneumonia and Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially caused by gram-negative bacteria
- Acute pyelonephritis,
- Complicated urinary tract infections and Bacterial prostatitis
- Genital tract infections i.e. gonococcal urethritis and cervicitis due to susceptible *Neisseria gonorrhoeae*, epididymo-orchitis including cases due susceptible to *Neisseria gonorrhoeae*, pelvic inflammatory disease including cases due susceptible to *Neisseria gonorrhoeae.*
- Infections of the gastro-intestinal tract (e.g., travelers' diarrhea)
- 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 meningitidis*
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)
- Neutropenic patients with fever that is suspected to be due to bacterial infection.

In exacerbations of chronic obstructive pulmonary disease & uncomplicated acute cystitis, Quinoflox should be used only when it is considered inappropriate to use other antibacterial agents

Children and adolescents

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

POSOLOGY AND METHOD OF ADMINISTRATION

Posology

The dosage is determined by the indication, the severity and the site of the infection, the susceptibility to Quinoflox of the causative organism(s), the renal function of the patient and, in children and adolescents the body weight. The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course.

Adults

Infections of the lower respiratory tract: 400mg twice daily to 400mg three times a day - 7 to 14 days

Infections of the upper respiratory tract:

- Acute exacerbation of chronic sinusitis: 400mg twice daily to 400mg three times a day - 7 to 14 days
- Chronic suppurative otitis media: 400mg twice daily to 400mg three times a day - 7 to 14 days
- Malignant external otitis: 400mg three times a day - 28 days up to 3 months

Urinary tract infections

- Acute and complicated pyelonephritis: 400mg twice daily to 400mg three times a day - 7 to 21 days, it can be continued for longer than 21 days in some specific circumstances (such as abscesses)
- Bacterial prostatitis: 400mg twice daily to 400mg three times a day - 2 to 4 weeks (acute)

Genital tract infections

- Epididymo-orchitis and pelvic inflammatory diseases including cases due to susceptible *Neiserria gonorrhoeae*: 400mg twice daily to 400mg three times a day - at least 14 days

Infections of the gastro-intestinal tract and intra-abdominal infections

- Diarrhoea caused by bacterial pathogens including Shigella spp. other than *Shigella dysenteriae* type 1 and empirical treatment of severe travellers' diarrhoea: 400mg twice daily - 1 day
- Diarrhoea caused by *Shigella dysenteriae* type 1: 400mg twice daily - 5 days
- Diarrhoea caused by *Vibrio cholerae*: 400mg twice daily - 3 days
- Typhoid fever: 400mg twice daily - 7 days
- Intra-abdominal infections due to Gram-negative bacteria: 400mg twice daily to 400mg three times a day - 5 to 14 days

Infections of the skin and soft tissue caused by Gram-negative bacteria: 400mg twice daily to 400mg three times a day - 7 to 14 days

Bone and joint infections: 400mg twice daily to 400mg three times a day - max. of 3 months

Neutropenic patients with fever suspected to be due to a bacterial infection: 400mg twice daily to 400mg three times a day. Therapy should be continued over the entire period of neutropenia.

- Ciprofloxacin should be co-administered with appropriate antibacterial agent(s) in accordance to official guidance

Inhalation anthrax post-exposure prophylaxis and curative treatment for persons requiring parenteral treatment

- Drug administration should begin as soon as possible after suspected or confirmed exposure: 400mg twice daily - 60 days from the confirmation of *Bacillus anthracis* exposure

Other severe infections: 10mg/kg body weight three times a day with a maximum of 400mg per dose.- According to the type of infections

Pediatric population

Cystic fibrosis: 10mg/kg body weight three times a day with a maximum of 400mg per dose. - 10 to 14 days

Complicated urinary tract infections and pyelonephritis: 6mg/kg body weight three times a day to 10mg/kg body weight three times a day with a maximum of 400mg per dose. - 10 to 21 days

Inhalation anthrax post-exposure prophylaxis and curative treatment for persons requiring parenteral treatment

- Drug administration should begin as soon as possible after suspected or confirmed exposure: 10mg/kg body weight twice daily to 15mg/kg body weight twice daily with a maximum of 400mg per dose. - 60 days from the confirmation of *Bacillus anthracis* exposure

Other severe infections: 10mg/kg body weight three times a day with a maximum of 400mg per dose. - According to the type of infections

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 or hepatic impairment

- Creatinine Clearance [mL/min/1.73m^2]: > 60, Serum Creatinine [µmol/L]: < 124 ->See Usual Dosage.
- Creatinine Clearance [mL/min/1.73m^2]: 30 – 60, Serum Creatinine [µmol/L]: 124-168 ->200-400 mg every 12 h.
- Creatinine Clearance [mL/min/1.73m^2]: < 30,Serum Creatinine [µmol/L]: >169 ->200-400mg every 24 h.
- Patients on hemodialysis- Serum Creatinine [µmol/L]: > 169 ->200-400 mg every 24 h (after dialysis).
- Patient on peritoneal dialysis-Serum cratinine [µmol/L] : >169 ->200-400mg every 24h.

In patients with impaired liver function no dose adjustment is required.
Dosing in children with impaired renal and/or hepatic function has not been 200-400mg studied.

Method of administration

Ciprofloxacin solution for infusion should be checked visually prior to use. It must not be used if cloudy. Ciprofloxacin Infusion should be administered by intravenous infusion. For children, the infusion duration is 60 minutes.
In adult patients, infusion time is 60 minutes for 400mg Ciprofloxacin solution for infusion and 30 minutes for 200mg Ciprofloxacin solution for infusion.
Slow infusion into a large vein will minimize patient discomfort and reduce the risk of venous irritation.
Ciprofloxacin solution for infusion should be administered without mixing with any other substances or infusion fluids. Unless compatibility is proven, the infusion solution should always be administered separately.
When ciprofloxacin infusion solutions are mixed with compatible infusion solutions, for microbial reasons and light sensitivity these solutions must be administered shortly after admixture.

CONTRAINDICATIONS:

- Hypersensitivity to the active substance, to other quinolones
- Concomitant administration of ciprofloxacin and tizanidine patients who have shown hypersensitivity to ciprofloxacin or any other quinolones
- Concomitant use of ciprofloxacin with other medicines known to prolong the QT interval
- Myasthenia gravis .
- A history of tendon, muscle, joint, central nervous system, epilepsy or psychotic disorders
- Aortic aneurysm and/or dissection or in patients with risk factors
- Patients with confirmed mitral valve and/or aortic valve regurgitation
- Concomitant use of fluoroquinolones with ACE inhibitors/angiotensin-receptor blockers in patients with moderate to severe renal impairment (creatinine clearance ≤ 30 mL/min) and in the elderly.

Special warnings and precautions for use

The use of ciprofloxacin should be avoided in patients who have experienced serious adverse reactions in the past when using quinolone or fluoroquinolone containing products

Prolonged, disabling and potentially irreversible serious adverse drug reactions

Ciprofloxacin should be discontinued immediately at the first signs or symptoms of any serious adverse reaction.

Severe infections and mixed infections with Gram-positive and anaerobic pathogens

In such infections Ciprofloxacin must be co administered with other appropriate antibacterial agents.

Streptococcal Infections (including *Streptococcus pneumoniae*)

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 urethritis or cervicitis only if Ciprofloxacin-resistant *Neisseria gonorrhoeae* can be excluded.

Urinary tract infections

Resistance to fluoroquinolones of *Escherichia coli* – the most common pathogen involved in urinary tract infections.

Travelers' diarrhea

The choice of ciprofloxacin should take into account information on resistance to ciprofloxacin in relevant pathogens in the countries visited.

Infections of the bones and joints

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

Inhalational anthrax

Treating physicians should refer to national and/or international consensus documents regarding the treatment of anthrax.

Pediatric Population

Ciprofloxacin treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

Complicated urinary tract infections and pyelonephritis

Ciprofloxacin treatment of urinary tract infections should be considered when other treatments cannot be used.

Musculoskeletal System

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

Tendinitis / tendon rupture/ Myasthenia gravis

At the first sign of tendinitis the treatment with Ciprofloxacin should be discontinued and alternative treatment should be considered. 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. Avoid direct exposure to either extensive sunlight or UV irradiation during treatment.

Central Nervous System

Ciprofloxacin like other quinolones is known to trigger seizures or lower the seizure threshold.

Cardiac disorders

Caution should be taken when using fluoroquinolones, including ciprofloxacin, in patients with known risk factors for prolongation of the QT interval such as, for example:

- Congenital long QT syndrome
- Concomitant use of drugs that are known to prolong the QT interval
- Uncorrected electrolyte imbalance
- Cardiac disease

Caution should be taken when using fluoroquinolones, including ciprofloxacin, in elderly populations

Dysglycemia

In diabetic patients, careful monitoring of blood glucose is recommended.

Gastrointestinal System

The occurrence of severe and persistent diarrhea during or after treatment may indicate an antibiotic-associated colitis. In such cases, ciprofloxacin should immediately be discontinued, and an appropriate therapy initiated.

Renal and urinary system

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

Impaired renal function

Since ciprofloxacin is largely excreted unchanged via the renal pathway dose adjustment is needed in patients with impaired renal function

Hepatobiliary system

In the event of any signs and symptoms of hepatic disease, treatment should be discontinued.

Glucose-6-phosphate dehydrogenase deficiency

Ciprofloxacin should be avoided in these patients unless the potential benefit is considered to outweigh the possible risk.

Resistance

There may be a particular risk of selecting for Ciprofloxacin-resistant bacteria during extended durations of treatment and when treating nosocomial infections and/or infections caused by Staphylococcus and Pseudomonas species.

Cytochrome P450

Ciprofloxacin inhibits CYP1A2 and thus may cause increased serum concentration of theophylline, clozapine, olanzapine, ropinirole, tizanidine, duloxetine, agomelatine.

Methotrexate

The concomitant use of ciprofloxacin with methotrexate is not recommended.

Interaction with tests

The in-vitro activity of Ciprofloxacin against Mycobacterium tuberculosis might give false negative bacteriological test results in specimens from patients currently taking Ciprofloxacin.

Aortic aneurysm and dissection, and heart valve regurgitation/incompetence

Fluoroquinolones should only be used after careful benefit-risk assessment and after consideration of other therapeutic options in patients with positive family history of aneurysm disease or congenital heart valve disease or in presence of other risk factors or conditions predisposing

Interaction with other medicinal products and other forms of interaction
Effects of other products on ciprofloxacin:
Drugs known to prolong QT interval: Ciprofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong QT interval
Probenecid: Co-administration of probenecid and ciprofloxacin increase ciprofloxacin serum concentrations.

Effects of ciprofloxacin on other medicinal products:
Tizanidine: must not be administered together with ciprofloxacin. There was an increase in serum tizanidine concentration when given concomitantly with 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 that may rarely be life-threatening or fatal
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.
Methotrexate: patients on methotrexate therapy should be carefully monitored when concomitant ciprofloxacin therapy is indicated.
NSAID: Concomitant administration of the nonsteroidal anti-inflammatory medicines with quinolones such as ciprofloxacin increases the risk of central nervous system stimulation and seizures.
Cyclosporin: It is frequently (twice a week) necessary to control the serum creatinine concentrations in patients who are using cyclosporin
Vitamin K antagonists: Simultaneous administration of ciprofloxacin with a vitamin K antagonist may augment its anti-coagulant effects. The INR should be monitored frequently during and shortly after co-administration of ciprofloxacin with a vitamin K antagonist (e.g. warfarin).
Duloxetine & Zolpidem: An increase of blood concentrations can be expected with concomitant administration with ciprofloxacin. Concurrent use is not recommended
Ropinirole: Monitoring of ropinirole-related side effects and dose adjustment as appropriate is recommended during and shortly after co-administration with ciprofloxacin.
Lidocaine: Concomitant use of lidocaine-(lignocaine)-containing medicines reduces the clearance of intravenous lidocaine by 22 % and may increase the risk for lidocaine side effects.
Clozapine: Clinical surveillance and appropriate adjustment of clozapine dosage during and shortly after co-administration with ciprofloxacin are advised
Sildenafil: Caution Should be used prescribing ciprofloxacin concomitantly with sildenafil taking into consideration the risks and the benefits.
ACE inhibitors and angiotensin-receptor blockers: Concomitant use of fluoroquinolones and ACE inhibitors/angiotensin-receptor blockers may precipitate acute kidney injury.

Pregnancy and lactation
Safety during pregnancy and lactation has not been established

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.

Effects on ability to drive and use machines
Due to its neurological effects, ciprofloxacin may affect reaction time. Thus, the ability to drive or to operate machinery may be impaired.

Undesirable effects
The most commonly reported adverse drug reactions (ADRs) are nausea and diarrhea. Adverse reactions have been ranked under headings of frequency using the following convention: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data).
Common: Nausea, Diarrhea
Uncommon: Mycotic superinfections, Eosinophilia, Decreased appetite, Psychomotor hyperactivity/agitation, Headache, Dizziness, Sleep disorders, Taste disorders, Increase in transaminases, Increased bilirubin, Rash, Pruritus, Urticaria, Musculoskeletal pain, Arthralgia, Renal impairment, Asthenia, Fever, Increase in blood alkaline phosphatase
Rare: Leukopenia, Anemia, Neutropenia, Leukocytosis, Thrombocytopenia, Thrombocythemia, Allergic reaction, Allergic edema/angioedema, Hyperglycemia, Hypoglycemia, Hypoglycemic coma, Confusion and disorientation, Anxiety reaction, Abnormal dreams, Depression, Hallucinations, Par- and Dysesthesia, Hypoesthesia, Tremor, Seizures, Vertigo, Visual disturbances, Tinnitus, Hearing loss, Tachycardia, Vasodilatation, Hypotension, Syncope, Dyspnea, Hepatic impairment, Cholestatic icterus, Hepatitis, Photosensitivity reactions, Myalgia, Arthritis, Increased muscle tone and cramping, Renal failure, Hematuria, Crystalluria, Tubulointerstitial nephritis, Oedema, Sweating (hyperhidrosis), Increased amylase
Very Rare: Hemolytic anemia, Agranulocytosis, Pancytopenia, Bone marrow depression, Anaphylactic reaction, Anaphylactic shock, Serum sickness-like reaction, Migraine, Disturbed coordination, Gait disturbance, Olfactory nerve disorders, Intracranial hypertension, Pseudotumor cerebri, Visual color distortions, Vasculitis, Liver necrosis, Petechiae, Erythema multiforme, Erythema nodosum, Stevens-Johnson Syndrome, Toxic epidermal necrolysis, Muscular weakness, Tendinitis, Tendon rupture, Exacerbation of myasthenia gravis
Frequency Not Known: Syndrome of inappropriate secretion of antidiuretic hormone (SIADH), Mania including hypomania, Peripheral neuropathy and polyneuropathy, Ventricular arrhythmia, ECG QT prolonged, Acute generalized exanthematous pustulosis (AGEP), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), International normalized ratio increased (in patients treated with Vitamin K antagonists)

The following undesirable effects have a higher frequency category in the subgroups of patients receiving intravenous or sequential (intravenous to oral) treatment:

Common: Vomiting, Transient increase in transaminases, Rash.
Uncommon: Thrombocytopenia, Thrombocythemia, Confusion and disorientation, Hallucinations, Par- and dysesthesia, Seizures, Vertigo, Visual disturbances, Hearing loss, Tachycardia, Vasodilatation, Hypotension, Transient hepatic impairment, Cholestatic icterus, Renal failure, Oedema.
Rare: Pancytopenia, Bone marrow depression, Anaphylactic shock, Psychotic reactions, Migraine, Olfactory nerve disorders, Hearing impaired, Vasculitis, Pancreatitis, Liver necrosis, Petechiae, Tendon rupture.

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.
Apart from routine emergency measures, e.g. ventricular emptying followed by medical carbon, it is recommended to monitor renal function, including urinary pH and acidify, if required, to prevent crystalluria. Patients should be kept well hydrated. Calcium or magnesium containing antacids may theoretically reduce the absorption of ciprofloxacin in overdoses.

PHARMACOLOGICAL PROPERTIES
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
Commonly Susceptible Species
Aerobic Gram-positive micro-organisms: *Bacillus anthracis, Aerobic Gram-negative micro-organisms: Aeromonas spp., Brucella spp., Citrobacter koseri, Francisella tularensis, Hemophilus ducreyi, Hemophilus influenzae, Legionella spp., Moraxella catarrhalis, Neisseria meningitidis, Pasteurella spp., Salmonella spp., Shigella spp., Vibrio spp. Yersinia pestis*

Anaerobic micro-organisms: *Mobiluncus*

Other micro-organisms: *Chlamydia trachomatis, Chlamydia pneumoniae, Mycoplasma hominis, Mycoplasma pneumoniae*

Species For Which Acquired Resistance May Be A Problem
Aerobic Gram-positive micro-organisms: *Enterococcus faecalis, Staphylococcus spp.*

Aerobic Gram-negative micro-organisms: *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*

Anaerobic micro-organisms: *Peptostreptococcus spp., Propionibacterium acnes*

Breakpoints
Spectrum of antibacterial activity
Breakpoints separate susceptible strains from strains with intermediate susceptibility and the later from resistant strains:

EUCAST Recommendations

Enterobacteriaceae	S ≤ 0.25mg/L	R > 0.5mg/L
Salmonella spp	S ≤ 0.06mg/L	R > 0.06mg/L
Pseudomonas spp.	S ≤ 0.5mg/L	R > 0.5mg/L
Acinetobacter spp.	S ≤ 1mg/L	R > 1mg/L
Staphylococcus spp.	S ≤ 1mg/L	R > 1mg/L
Haemophilus influenzae	S ≤ 0.06mg/L	R > 0.06mg/L
Moraxella catarrhalis	S ≤ 0.125mg/L	R > 0.125mg/L

Neisseria gonorrhoeae	S ≤ 0.03mg/L	R > 0.06mg/L
Neisseria meningitidis	S ≤ 0.03mg/L	R > 0.03mg/L
Non-species-related breakpoints	S ≤ 0.25mg/L	R > 0.5mg/L

PHARMACOKINETIC PROPERTIES

Absorption
Following an intravenous infusion of ciprofloxacin the mean maximum serum concentrations were achieved at the end of infusion. Pharmacokinetics of ciprofloxacin were linear over the dose range up to 400mg administered intravenously.

Distribution
Protein binding of ciprofloxacin is low (20-30%). Ciprofloxacin is present in plasma largely in a non-ionized form and has a large steady state distribution volume of 2-3 L/kg body weight.

Biotransformation
Low concentrations of four metabolites have been reported, which were identified as: desethyleneciprofloxacin (M1), sulphociprofloxacin (M2), oxociprofloxacin (M3) and formylciprofloxacin (M 4). Ciprofloxacin is known to be a moderate inhibitor of the CYP 450 1A2 iso-enzymes.

Elimination
Ciprofloxacin is largely excreted unchanged both renally and, to a smaller extent, faecally. Renal clearance is between 180-300 mL/kg/h and the total body clearance is between 480-600 mL/kg/h. Ciprofloxacin is present in the bile in high concentrations.

PHARMACEUTICAL PARTICULARS

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned in section.

Shelf life
Quinoflox 100mg/50mL Infusion: 3 years
Quinoflox 200mg/100mL Infusion: 3 years
Quinoflox DS 400mg/100mL Infusion: 2 years

Special Precautions for Storage
Protect from heat & sunlight, store below 25°C.
At cool storage temperatures, precipitation may occur which will re-dissolve at room temperature. It is, therefore, recommended not to store the infusion solution in a refrigerator.
Quinoflox should not be administered after the expiry date.
Do not refrigerate or freeze.
The expiration date refers to the product correctly stored at the required condition.
Do not use if solution contains undissolved particle.
Keep out of the reach of children.
To be sold on the prescription of a registered medical practitioner only.

Presentation
Quinoflox 100mg/50mL
1 vial of 50mL infusion solution containing 100mg ciprofloxacin.
Quinoflox 200mg/100mL
1 vial of 100mL infusion solution containing 200mg ciprofloxacin.
Quinoflox DS 400mg/100mL
1 vial of 100mL infusion solution containing 400mg ciprofloxacin

Marketing Authorisation Holder
Head office:
Bosch Pharmaceuticals (Pvt.) Ltd., 8, Modern Society, Tipu Sultan Road, Karachi-75350 (Pakistan).

Manufacturing site:
Bosch Pharmaceuticals (Pvt.) Ltd., Plot No. 209, Sector 23, Korangi Industrial area, Karachi Pakistan
Manufactured for:
Bosch Pharmaceuticals (Pvt.) Ltd., Plot No. 221-223, Sector 23, Korangi Industrial area, Karachi Pakistan

Marketing Authorisation Number(S)
Quinoflox 100mg/50mL Infusion: 023020
Quinoflox 200mg/100mL Infusion: 023021
Quinoflox DS 400mg/100mL Infusion: 048489

Date Of First Authorisation/Renewal Of The Authorisation
Quinoflox 100mg/50mL Infusion: 04-03-1999 / 03-03-2019
Quinoflox 200mg/100mL Infusion: 04-03-1999 / 03-03-2019
Quinoflox DS 400mg/100mL Infusion:09-02-2008 / 08-02-2023

DATE OF REVISION OF THE TEXT
22-12-2023

ہدایات:
- گرمی اور دھوپ سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
- ریفریجریٹر میں رکھنے یا منجمد ہونے سے بچائیں۔
- محلول میں کوئی غیر حل پذیر ذرات نظر آنے کی صورت میں ہرگز استعمال نہ کریں۔
- بچوں کی پہنچ سے دور رکھیں۔ - صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
Bosch Pharmaceuticals (Pvt.) Ltd.
209, Sector 23, Korangi Industrial Area, Karachi - Pakistan.
For **Bosch Pharmaceuticals (Pvt.) Ltd.**
221-223, Sector 23, K.I.A. Karachi-Pakistan.
Mfg. Lic. No.: 000350

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