Bosch

For Medical Professional only

QILOX®

(Ciprofloxacin U.S.P.)

200mg/100ml & 400mg/100ml Infusion

کیلوکس

(سپروفلاکساسن یو۔ایس۔پی)

۲۰۰ ملی گرام/۱۰۰ ملی لیٹر - ۴۰۰ ملی گرام/۱۰۰ ملی لیٹر

COMPOSITION

Active constituents

Qilox 200mg (Infusion solution): 1 vial of 100ml infusion solution contains 254.4 mg ciprofloxacin lactate, corresponding to 200mg ciprofloxacin.

Qilox 400mg DS (Infusion solution): 1 vial of 100 ml infusion solution contains 508.8 mg ciprofloxacin lactate, corresponding to 400mg ciprofloxacin.

900mg sodium chloride for 100ml infusion.

Further constituents:

lactic acid, sodium chloride, hydrochloric acid, water for injections.

THERAPEUTIC INDICATIONS:

QILOX (Ciprofloxacin) 200mg/100ml & 400mg/100ml solution for infusion is indicated for the treatment of the following infections. Special attention should be paid to available information on resistance to ciprofloxacin before commencing therapy.

Adults

- Lower respiratory tract infections due to Gram-negative bacteria
  - exacerbations of chronic obstructive pulmonary disease
  In exacerbations of chronic obstructive pulmonary disease Ciprofloxacin should be used only when it is considered inappropriate to use other antibacterial agents that are commonly recommended for the treatment of these infections.
  - broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
  - pneumonia
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria
- Acute pyelonephritis
- Bacterial prostatitis
- Genital tract infections
  - epididymo-orchitis including cases due to susceptible Neisseria gonorrhoeae
  - pelvic inflammatory disease including cases due to susceptible Neisseria gonorrhoeae
- Infections of the gastro-intestinal tract (e.g. travellers` diarrhoea)
- Intra-abdominal infections
- Complicated skin and skin structure infections/complicated skin and soft tissue infections
- Malignant external otitis
- Infections of the bones and joints
- 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 acute pyelonephritis
- Inhalation anthrax (post-exposure prophylaxis and curative treatment)
  Ciprofloxacin may also be used to treat severe infections in children and adolescents when this is considered to be necessary.

Treatment should be initiated only by physicians who are experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents. Consideration should be given to official guidance on the appropriate use of antibacterial agents

DOSAGE:

Dosage of QILOX (ciprofloxacin) infusion depends on the indication, the severity and the site of the infection, the susceptibility to ciprofloxacin of the causative organism(s), the renal function of the patient and, in children and adolescents the body weight.

Treatment of some infections (e.g. pelvic inflammatory disease, intra-abdominal infections, infections in neutropenic patients and infections of bones and joints) may require co-administration with other appropriate antibacterial agents depending on the pathogens involved.

Adults

Indications		Daily dose in mg
Infections of the lower respiratory tract		400 mg twice daily to 400 mg three times a day
Infections of the upper respiratory tract Ear infections	Acute exacerbation of chronic sinusitis	400 mg twice daily to 400 mg three times a day
	Chronic suppurative otitis media	400 mg twice daily to 400 mg three times a day
	Malignant external otitis	400 mg three times a day
Urinary tract infections	Acute pyelonephritis	400 mg twice daily to 400 mg three times a day
	Bacterial prostatitis	400 mg twice daily to 400 mg three times a day
Genital tract infections	Epididymo-orchitis and pelvic inflammatory diseases	400 mg twice daily to 400 mg three times a day
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' diarrhea	400 mg twice daily
	Diarrhoea caused by Shigella dysenteriae type 1	400 mg twice daily
	Diarrhoea caused by Vibrio cholera	400 mg twice daily
	Typhoid fever	400 mg twice daily
	Intra-abdominal infections due to Gram-negative bacteria	400 mg twice daily to 400 mg three times a day
Complicated skin and structure infections/ complicated skin and soft tissue infections		400 mg twice daily to 400 mg three times a day
Infections of the bones and joints		400 mg twice daily to 400 mg three times a day
Management of neutropenic patients with fever Ciprofloxacin should be co-administered with appropriate antibacterial agent(s) in accordance to official guidance		400 mg three times daily to 400 mg three times a day
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.		400 mg twice daily

Pediatric population

Indications	Daily dose in mg
Broncho-pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis	10 mg/kg body weight three times a day with a maximum of 400 mg per dose.
Complicated urinary tract infections and acute pyelonephritis	6 mg/kg body weight three times a day to 10 mg/kg body weight three times a day with a maximum of 400 mg per dose.
Inhalation anthrax post-exposure curative treatment for persons requiring parenteral treatment Drug administration should begin as soon as possible after suspected or confirmed exposure.	10 mg/kg body weight twice daily to 15 mg/kg body weight twice daily with a maximum of 400 mg per dose.
Other severe infections	10 mg/kg body weight three times a day with a maximum of 400 mg 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 m²]	Intravenous Dose [mg]
> 60	See usual dosage.
30 – 60	200 – 400 mg every 12 h
< 30	200 – 400 mg every 24 h
Patients on haemodialysis	200 – 400 mg every 24 h (after dialysis)
Patients on peritoneal dialysis	200 – 400 mg every 24 h

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

METHOD OF ADMINISTRATION:

Ciprofloxacin should be administered by intravenous infusion. The solution should be visually inspected prior to use and only clear solutions, without particles, should be used.
For children, the infusion duration is 60 minutes.
In adult patients, infusion time is 60 minutes for 400 mg Ciprofloxacin and 30 minutes for 200 mg Ciprofloxacin. Slow infusion into a large vein will minimize patient discomfort and reduce the risk of venous irritation.
The infusion solution can be infused either directly or after mixing with other compatible infusion solutions.

CONTRAINDICATIONS:

Ciprofloxacin (QILOX) must not be used in cases of hypersensitivity to ciprofloxacin or other quinolone chemotherapeutics.
Concomitant administration of ciprofloxacin and tizanidine

COMPATIBILITIES:

The Ciprofloxacin (QILOX) infusion solution is compatible with physiological saline i.e. Ringer solution and Ringer lactate solution, 5% and 10% glucose solutions, 10% fructose solution, and 5% glucose solution with 0.225% NaCl or 0.45% NaCl.

When Ciprofloxacin (QILOX) infusion solutions are mixed with compatible infusion solution for microbiological reasons and light sensitivity these solutions should be administered shortly after admixture.

INCOMPATIBILITIES:

Unless compatibility with infusion solutions / drugs has been confirmed, the infusion solution must always be administered separately. The visual signs of incompatibility are e.g. precipitation, clouding, and discoloration. Incompatibility appears with all infusion solutions/drugs that are physically or chemically unstable at the pH of the solution (e.g. penicillins, heparin solutions), especially on combination with solutions adjusted to an alkaline pH (pH of the QILOX infusion: 3.9-4.5).

Since the infusion solution is photosensitive, the infusion bottles should be removed from the box only immediately before use.

ADVERSE EFFECTS:
Ciprofloxacin is generally well tolerated. The most commonly reported adverse drug reactions (ADRs) are nausea and diarrhea, vomiting, transient increase in transaminases, rash, and injection and infusion site reactions.

Common: Nausea, diarrhea, infusion site reactions.
Uncommon: Mycotic superinfections, eosinophilia, anorexia, psychomotor,hyperactivity/agitation, headache, dizziness, sleep disorders, taste disorders, vomiting, gastrointestinal and abdominal pains, dyspepsia, flatulence, increase in transaminases, increased bilirubin, rash, pruritus, urticaria, musculoskeletal pain (e.g., extremity pain, back pain, chest pain), arthralgia, renal impairment, asthenia, fever, increase in blood alkaline phosphatase.

Rare: Antibiotic associated colitis (very rarely with possible fatal outcome), leukopenia, anemia, neutropenia, leukocytosis, thrombocytopenia, thrombocytemia, allergic reaction, allergic oedema/angioedema, hyperglycemia, confusion and disorientation, anxiety reaction, abnormal dreams, depression, hallucinations, paresthesia and dysesthesia, hypoesthesia, tremor, seizures, vertigo, visual disturbances, tinnitus, hearing loss/hearing impairment tachycardia, vasodilatation, hypotension, syncope, dyspnea (including asthmatic condition), hepatic impairment, cholestatic icterus, hepatitis, photosensitivity reactions, myalgia, arthritis, increased muscle tone and cramping, renal failure, hematuria, crystalluria, tubulointerstitial nephritis, oedema, sweating (hyperhidrosis), abnormal prothrombin level, increased amylase.

Very rare: Hemolytic anemia, agranulocytosis, pancytopenia (life-threatening), bone marrow depression (life-threatening), anaphylactic reaction, anaphylactic shock (lifethreatening), serum sickness-like reaction, psychotic reactions, migraine, disturbed coordination, gait disturbance, olfactory nerve disorders, intracranial hypertension, visual colour distortions, vasculitis, pancreatitis, liver necrosis (very rarely progressing to life threatening hepatic failure), petechiae, erythema multiforme, erythema nodosum, Stevens-Johnson syndrome (potentially life-threatening), toxic epidermal, necrolysis (potentially life-threatening), muscular weakness, tendinitis, tendon rupture, exacerbation of symptoms of myasthenia gravis.

PRECAUTIONS & WARNING:
Musculoskeletal System: Fluoroquinolones, including Ciprofloxacin, are associated with an increased risk of tendinitis and tendon rupture in all ages. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is increased in patients over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants, strenuous physical activity, renal failure, and previous tendon disorders such as rheumatoid arthritis. Avoid Ciprofloxacin in patients with known history of myasthenia gravis.

Peripheral neuropathy: Ciprofloxacin should be discontinued in patients experiencing symptoms of neuropathy, including pain, burning, tingling, numbness, and/or weakness in order to prevent the development of an irreversible condition.

Central nervous system: Ciprofloxacin should be used with caution in patients with CNS disorders which may be predisposed to seizure.

Genital tract infections: For epididymo-orchitis and pelvic inflammatory diseases, empirical ciprofloxacin should only be considered in combination with another appropriate antibacterial agent (e.g. a cephalosporin) unless ciprofloxacin-resistant Neisseria gonorrhoeae can be excluded.

Complicated urinary tract infections and pyelonephritis: Ciprofloxacin treatment of urinary tract infections should be considered when other treatments cannot be used, and should be based on the results of the microbiological documentation.

Hypersensitivity: Hypersensitivity and allergic reactions, including anaphylaxis and anaphylactoid reactions, may occur following a single dose and may be life-threatening. If such reaction occurs, ciprofloxacin should be discontinued.

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.

Cardiac disorders: Caution should be taken when using ciprofloxacin in patients with known risk factors for prolongation of the QT interval. Elderly patients and women may be more sensitive to QTc-prolonging medications. Therefore, caution should be taken when using ciprofloxacin in these populations.

Risk of Aortic Aneurysm and Dissection: 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 in patients diagnosed with pre-existing aortic aneurysm and/or aortic dissection, or in presence of other risk factors or conditions predisposing for aortic aneurysm and dissection (e.g. Marfan syndrome, vascular Ehlers-Danlos syndrome, Takayasu arteritis, giant cell arteritis, Behcet's disease, hypertension, known atherosclerosis).

Gastrointestinal system: Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Ciprofloxacin, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued.

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.

Hepatobiliary system: Cases of hepatic necrosis and life-threatening hepatic failure have been reported with ciprofloxacin. In the event of any signs and symptoms of hepatic disease (such as anorexia, jaundice, dark urine, pruritus, or tender abdomen), treatment should be discontinued.

Glucose-6-phosphate dehydrogenase deficiency: Ciprofloxacin should be avoided in patients with glucose-6-phosphate dehydrogenase deficiency, unless the potential benefit is considered to outweigh the possible risk. In this case, potential occurrence of haemolysis should be monitored.

Injection site reaction: Local intravenous site reactions have been reported with the intravenous administration of ciprofloxacin. These reactions are more frequent if the infusion time is 30 minutes or less. 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.

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.

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

NaCl Load: In patients for whom sodium intake is of medical concern (patients with congestive heart failure, renal failure, nephrotic syndrome, etc.), the additional sodium load should be taken into account.

Hypoglycemia: As with other quinolones, hypoglycemia has been reported most often in diabetic patients, predominantly in the elderly population. In all diabetic patients, careful monitoring of blood glucose is recommended.

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

USE IN PREGNANCY AND BREAST-FEEDING:
Pregnancy
Pregnancy Category: C
There are no adequate and well-controlled studies in pregnant women. QILOX should not be used during pregnancy unless the potential benefit justifies the potential risk to both fetus and mother.

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

DRUG INTERACTION:
Drugs known to prolong QT interval: Ciprofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong the QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

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

Drugs metabolized by cytochrome enzyme: Co-administration of QILOX with other drugs primarily metabolized by CYP1A2 results in increased plasma concentrations of these drugs and could lead to clinically significant adverse events of the co-administered drug.

Tizanidine: Tizanidine must not be administered together with ciprofloxacin. Increased serum tizanidine concentration is associated with a potentiated hypotensive and sedative effect.

Methotrexate: Renal tubular transport of methotrexate may be inhibited by concomitant administration of ciprofloxacin, potentially leading to increased plasma levels of methotrexate and increased risk of methotrexate-associated toxic reactions. The concomitant use is not recommended.

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. During the combination, serum theophylline concentrations should be checked and the theophylline dose reduced as necessary.

Manufactured by:
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Vitamin K antagonists: Simultaneous administration of ciprofloxacin with a vitamin K antagonist may augment its anticoagulant effects. The risk may vary with the underlying infection, age and general status of the patient so that the contribution of ciprofloxacin to the increase in INR (international normalized ratio) is difficult to assess. The INR should be monitored frequently during and shortly after coadministration of ciprofloxacin with a vitamin K antagonist.

Glyburide: The concomitant administration of ciprofloxacin with the sulfonylurea glyburide has resulted in severe hypoglycemia

Glibenclamide: Concurrent administration of ciprofloxacin and glibenclamide can intensify the action of glibenclamide.

OVERDOSE:
Symptoms in overdose consist of dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria and haematuria. Reversible renal toxicity has been reported.
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. Only a small quantity of ciprofloxacin (<10%) is eliminated by haemodialysis or peritoneal dialysis.

In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

STORAGE AND INSTRUCTIONS:
Protect from heat & sunlight, store below 25°C.
Do not refrigerate or freeze.
The expiration date refer to the product correctly stored at the required condition.
Do not use if solution contains undissolved particle.
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:
Qilox 200mg/100ml
1 vial of 100ml infusion solution containing 200mg ciprofloxacin.

Qilox 400mg/100ml
1 vial of 100ml infusion solution containing 400mg ciprofloxacin.

ہدایات:

- گرمی اور روشنی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
- ریفریجریٹر میں رکھنے یا جمنے 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۔

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