

Ciprofloxacin

Ciprofloxacin lactate equivalent to Ciprofloxacin 2mg/mL

Presentation

Ciprofloxacin 2mg/mL is a clear, colourless to slightly yellow infusion solution containing ciprofloxacin lactate equivalent to 2mg of Ciprofloxacin per mL. The product comes in bottles of 50mL which contain 100mg ciprofloxacin, 100mL which contain 200mg ciprofloxacin and 200mL which contain 400mg ciprofloxacin

Uses

Actions

Ciprofloxacin is a synthetic carboxyquinolone derivative with broad spectrum antibacterial activity. It acts by inhibiting the A subunit of DNA gyrase (topoisomerase) which is essential in the reproduction of bacterial DNA.

Resistance to ciprofloxacin develops slowly and in stages.

Plasmid-mediated resistance development of the kind that occurs with β -lactam antibiotics, aminoglycosides and tetracyclines has not been observed with ciprofloxacin. It is of clinical interest that plasmid-carrying bacteria are also completely sensitive to ciprofloxacin.

Parallel resistance to other active substance groups such as β -lactam antibiotics, aminoglycosides, tetracyclines, macrolide or peptide antibiotics, sulphonamides, trimethoprim or nitrofurans derivatives is not generally seen with ciprofloxacin. Ciprofloxacin is effective on pathogens resistant to the above mentioned groups of antibiotics.

Parallel resistance is observed within the group of gyrase inhibitors. However because of the high primary sensitivity to ciprofloxacin shown by most organisms, parallel resistance is less pronounced with this drug, Ciprofloxacin is often effective on pathogens that are resistant to the less effective gyrase inhibitors.

According to in-vitro investigations, the following pathogens can be regarded as sensitive:

E. coli, Shigella, Salmonella, Citrobacter, Klebsiella, Enterobacter, Serratia, Hafnia, Edwardsiella, Proteus (indole-positive and indole-negative), Providencia, Morganella, Yersinia; Vibrio, Aeromonas, Plesiomonas, Pasteurella, Haemophilus, Campylobacter, Pseudomonas, Legionella, Neisseria, Moraxella, Acinetobacter, Brucella; Staphylococcus, Listeria, Corynebacterium, Chlamydia.

The following show varying degrees of sensitivity:

Gardnerella, Flavobacterium, Alcaligenes, Streptococcus agalactiae, Enterococcus faecalis, Streptococcus pyogenes, Streptococcus pneumoniae, Viridans group Streptococci, Mycoplasma hominis, Mycobacterium tuberculosis, and Mycobacterium fortuitum.

The following are usually resistant:

Enterococcus faecium, Ureaplasma urealyticum, Nocardia asteroides.

With a few exceptions anaerobes are moderately sensitive e.g. *Peptococcus, Peptostreptococcus, Bacteroides.*

Ciprofloxacin has been shown to be active against *Bacillus anthracis* both in vitro and by use of serum levels as a surrogate marker.

Ciprofloxacin is ineffective against *Treponema pallidum.*

Ciprofloxacin is less active when tested in acidic pH. The inoculum size has little effect when tested in vitro. Minimal bactericidal concentration (MBC) is generally not more than double the minimal inhibitory concentration (MIC).

In vitro studies have shown that additive activity often results when ciprofloxacin is used in combination with other agents e.g. β -lactams, aminoglycosides, clindamycin, metronidazole.

Pharmacokinetics

Immediately following a 30 minute I.V. infusion of ciprofloxacin 200mg serum concentrations average 3 μ g/mL. During the first hour after completion of infusion serum concentration decreases to approximately 30% of the peak value but after that serum concentrations decline with a half-life of approximately 4 hours.

Time (post dose)	End of Infusion	0.5 hours	1 hour	3 hours	6 hours	8 hours	12 hours
Serum concentration (microgram/mL)	3.2	1.4	1.0	0.5	0.3	0.2	0.1

Pharmacokinetics of ciprofloxacin are linear over the dose range 100-400mg administered intravenously.

Approximately 50-70% of an intravenous dose is excreted unchanged in the urine. During the first 2 hours after a 200mg IV dose, the urine concentration of ciprofloxacin usually exceeds 200 μ g.

Comparison of the pharmacokinetic parameters for a twice daily and three times daily i.v. dose regimen indicated no evidence of drug accumulation for ciprofloxacin and its metabolites.

Metabolism

Four metabolites, desethyleneciprofloxacin (M_1), sulfociprofloxacin (M_2), oxociprofloxacin (M_3) and formylciprofloxacin (M_4) have been identified in human urine, which together account for approximately 12% of an intravenous dose. The metabolites have less antimicrobial activity than unchanged ciprofloxacin.

Excretion

Urinary excretion of ciprofloxacin is virtually complete within 24 hours after dosing. The renal clearance of ciprofloxacin is approximately 18L/hour which exceeds the normal glomerular filtration rate of 7.2L/hour. Therefore active tubular secretion would seem to play a significant role in its elimination.

Although bile concentrations of ciprofloxacin are 3-4 times higher than serum concentrations after intravenous dosing less than 1% is recovered from bile as unchanged drug. A further 1-2% of the dose is recovered from bile in the form of metabolites.

Approximately 15% of an intravenous dose is recovered from the faeces within 5 days after dosing.

Distribution

Protein binding of ciprofloxacin is low (20-30%), and the substance is present in plasma largely in a non-ionised form. Ciprofloxacin can diffuse freely into the

extravascular space. The large steady-state volume of distribution of 2-3 l/kg body weight shows that ciprofloxacin penetrates into tissues resulting in concentrations which clearly exceed the corresponding serum levels.

Non-renal clearance of ciprofloxacin is mainly due to active transintestinal secretion as well as metabolism. 1% of the dose is via the biliary excreted route. Ciprofloxacin is present in the bile in high concentrations.

Children

In a study in children, C_{max} and AUC were not age-dependent. In 10 children with severe sepsis, less than 1 year of age C_{max} was 6.1 mg/L (range 4.6 - 8.3 mg/L) after a 1-hour intravenous infusion at a dose level of 10 mg/kg; and 7.2 mg/L (range 4.7 - 11.8 mg/L) for children between 1 and 5 years of age. The AUC-values were 17.4 mg*h/L (range 11.8 - 32.0 mg*h/L) and 16.5 mg*h/L (range 11.0 - 23.8 mg*h/L) in the respective age groups. These values are within the range reported for adults at therapeutic doses. Based on population pharmacokinetic analysis of paediatric patients with various infections, the predicted mean half-life in children is approx. 4 -5 hours.

Elderly patients

The higher levels of ciprofloxacin and its metabolites seen in elderly patients are possibly due to reduced renal function and volume of distribution.

Impaired Renal Function

In patients with creatinine clearance 21-40mL/minutes, the half-life of ciprofloxacin is slightly prolonged but dosage adjustments are not usually required.

In patients with creatinine clearance <20mL/minute, the half-life is nearly doubled and dosage adjustments are necessary. Serum metabolite concentrations (especially M_2 and M_3) are higher than in patients with normal renal function.

Indications

Adults

Uncomplicated and complicated infections caused by ciprofloxacin sensitive pathogens:

Infections of the lower respiratory tract

In the treatment of outpatients with pneumonia due to *Pneumococcus*, ciprofloxacin should not be used as a drug of first choice. Ciprofloxacin can be regarded as a suitable treatment for pneumonias caused by *Klebsiella*, *Enterobacter*, *Proteus*, *E. coli*, *Pseudomonas*, *Haemophilus*, *Branhamella*, *Legionella*, and *Staphylococcus*

Infections of the kidneys and/or the efferent urinary tract

Infections of the genital organs, including adnexitis, gonorrhoea and prostatitis

Infections of the abdominal cavity (e.g. infections of the gastrointestinal tract or the biliary tract, peritonitis)

Infections of the skin and soft tissue

Infections of the bones and joints

Sepsis

Inhalation anthrax (post-exposure): To reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*. Ciprofloxacin serum concentrations achieved in humans serve as a surrogate endpoint reasonably likely to predict clinical benefit and provide the basis for this indication.

Children

For the treatment of acute pulmonary exacerbation of cystic fibrosis associated with *P. aeruginosa* infection in paediatric patients aged 5-17 years.

For the indication of inhalational anthrax (post-exposure).

Complicated urinary tract infections and pyelonephritis

For complicated urinary tract infections or pyelonephritis due to *E.coli* in paediatric patients aged 1-17 years.

The risk-benefit assessment indicates that administration of ciprofloxacin to paediatric patients is appropriate. Treatment should only be initiated after careful benefit/risk evaluation, due to possible adverse events related to joints and/or surrounding tissues. The use of ciprofloxacin for other indications is not recommended in children.

Dosage and Administration

Ciprofloxacin solution for infusion should be administered by intravenous infusion over a period of 60 minutes. 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 compatible infusion solutions.

Unless compatibility with other infusion solutions/drugs has been confirmed, the infusion solution must always be administered separately. The visual signs of incompatibility include precipitation, clouding and discolouration.

Incompatibility appears with all infusion solutions/drugs that are physically or chemically unstable at the pH of the solution (e.g. penicillins and heparin solutions), especially in combination with solutions adjusted to an alkaline pH. The pH of the ciprofloxacin solution is 3.9-4.5.

Adults:

Unless otherwise prescribed the following guideline doses are recommended:

Respiratory tract infection:

200-400mg at 12-hourly intervals depending upon severity and organism

Urinary tract infections:

Acute, uncomplicated - 100mg at 12-hourly intervals

Cystitis in women (before menopause) - a single dose of 100mg

Complicated - 200mg at 12-hourly intervals

Gonorrhoea:

Extragenital - 100mg at 12-hourly intervals

Acute, uncomplicated - a single dose of 100mg

Diarrhoea: 200mg at 12-hourly intervals

Other infections (see indications):

200-400mg at 12-hourly intervals

Severe, life threatening infections e.g. Streptococcal pneumonia, recurrent infections in cystic fibrosis, bone and joint infections, septicaemia, peritonitis. In particular when

Pseudomonas, *Staphylococcus* or *Streptococcus* is present.:

400mg at 8-hourly intervals

Inhalation anthrax (post exposure):

400mg at 12-hourly intervals. Drug administration should begin as soon as possible after suspected or confirmed exposure.

Elderly

Elderly patients should receive as low a dose as possible depending on the severity of their illness and the creatinine clearance.

Children

Clinical and pharmacokinetic data support the use of ciprofloxacin in paediatric cystic fibrosis patients (aged 5-17 years) with acute pulmonary exacerbation associated with *P. aeruginosa* infection, at a dose of 10mg/kg i.v. three times daily with a maximum daily dose of 1200mg.

For the indication of inhalational anthrax (post-exposure), the risk-benefit assessment indicates that treatment of paediatric patients with ciprofloxacin is appropriate. For paediatric patients, the recommended intravenous infusion dose is 10 mg/kg twice daily (not to exceed a maximum dose of 400 mg per dose, 800 mg per day). Drug administration should begin as soon as possible after suspected or confirmed exposure.

For the indication of complicated urinary tract infections and pyelonephritis, the recommended dose is 6 to 10 mg/kg i.v. every 8 hours with a maximum of 400 mg per dose.

Duration of Treatment

The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course. It is essential to continue therapy for at least 3 days after disappearance of the fever or the clinical symptoms.

Mean duration of treatment:

- 1 day for acute uncomplicated gonorrhoea and cystitis
- up to 7 days for infections of the kidneys, urinary tract and abdominal cavity
- a maximum of 2 months in osteomyelitis
- 60 days in inhalational anthrax (post-exposure)
- 7-14 days in all other infections
- In streptococcal infections the treatment must last at least 10 days because of the risk of late complications.
- Infections caused by Chlamydia should be treated for a minimum of 10 days.

Children

- For acute pulmonary exacerbation of cystic fibrosis associated with *P. aeruginosa* infection in paediatric patients aged 5-17 years the duration of treatment is 10-14 days.
- For inhalational anthrax (post-exposure), the duration of treatment is 60 days.
- For complicated urinary tract infections or pyelonephritis due to *E. coli*, the duration of treatment is 10-21 days.

Renal Impairment

Where creatinine clearance is between 31-60 mL/min/1.73m² or where the serum creatinine concentration is between 1.4-1.9 mg/100 mL the maximum daily dose for an intravenous regimen should be 800mg per day.

Where creatinine clearance is equal to or less than 30 mL/min/1.73m² or where the serum creatinine concentration is equal to or greater than 2.0 mg/100 mL the maximum daily dose for an intravenous regimen should be 400mg per day.

Where the patient has renal impairment and is receiving dialysis the dose for an intravenous regimen should be 400mg per day and after dialysis on dialysis days.

Where the patient has renal impairment plus CAPD, Ciprofloxacin infusion should be added to the intraperitoneal dialysate at the rate of 50mg ciprofloxacin per litre dialysate administered every 6 hours.

Dosing in children with impaired renal function has not been studied.

Hepatic Impairment

No dose adjustment is required for impaired liver function.

Dosing in children with impaired hepatic function has not been studied.

Contraindications

Hypersensitivity to ciprofloxacin or other quinolone chemotherapeutics.

Concurrent administration of ciprofloxacin and tizanidine is contraindicated because an undesirable increase in serum tizanidine concentrations associated with clinically relevant tizanidine-induced side effects (hypotension, somnolence, drowsiness) can occur.

Ciprofloxacin must not be prescribed for pregnant women or nursing mothers as there is no experience regarding safety in these patient groups and on the basis of animal studies, it is possible that the drug may cause damage to articular cartilage in the foetus or infant. Animal studies have not shown any evidence of teratogenic effects. When considering treatment for inhalational anthrax (post-exposure), the risks and benefits of ciprofloxacin and alternative antibiotic therapies must be carefully considered, and explained to the patient.

Warnings and Precautions

- Ciprofloxacin may cause tendonitis, tendon rupture or hypoglycaemia.
- The risk of tendonitis or tendon rupture is increased in patients: over the age of 60 years; on concomitant systemic steroid therapy; who have received a kidney, heart or lung transplant
- Ciprofloxacin should not be used in patients with a history of fluoroquinolone associated tendonopathy
- Tendonitis and tendon rupture risk is present during use and for 6 months following use of ciprofloxacin
- Prescribers should advise patients that at the first sign of tendon pain, inflammation or tendon rupture, to stop using ciprofloxacin, avoid exercise or use of the affected area and immediately contact their doctor.

Paediatric Use

Ciprofloxacin has been shown to cause arthropathy in weight-bearing joints of immature animals. Analysis of available data from Ciprofloxacin use in patients less than 18 years of age (the majority of whom had cystic fibrosis) did not disclose any evidence of drug related cartilage or articular damage. The use of Ciprofloxacin for indications other than the treatment of acute pulmonary exacerbation of cystic fibrosis caused by *P. aeruginosa* infection (children aged 5-17 years), complicated urinary tract infections and pyelonephritis due to *E. coli* (children aged 1-17 years)

and for the use in inhalation anthrax (post-exposure) was not studied. For other indications clinical experience is limited.

For the indication of inhalational anthrax (post-exposure), the risk-benefit assessment indicates that administration of ciprofloxacin to paediatric patients is appropriate.

Cytochrome P450

Ciprofloxacin is a moderate inhibitor of the CYP 450 1A2 enzymes. Care should be taken when other drugs are administered concomitantly which are metabolised via the same enzymatic pathway e.g. theophylline, methylxantines, caffeine. Increased plasma concentrations associated with drug specific side effects may be observed due to inhibition of their metabolic clearance by ciprofloxacin.

Gastrointestinal System

A doctor must be consulted in the event of severe or persistent diarrhoea during or after treatment, because of the possibility that this may be concealing pseudomembranous colitis with a potentially fatal outcome. In such cases, Ciprofloxacin must be discontinued and appropriate therapy (e.g. oral vancomycin 4 x 250mg daily) initiated. Drugs that inhibit peristalsis are contraindicated.

A temporary increase in transaminases, alkaline phosphatase or cholestatic jaundice may occur especially in patients with previous hepatic damage.

Nervous System

Ciprofloxacin should only be used in epileptics and patients who have suffered from previous CNS-disorders e.g. lowered convulsion threshold, previous history of convulsion, reduced cerebral blood flow, altered brain structure or stroke, where the benefits exceed the risks due to possible central-nervous effects. In some cases CNS reactions occurred after the first administration of Ciprofloxacin. In rare cases, depression or psychosis can progress to self-endangering behaviour. In these cases ciprofloxacin is to be discontinued immediately.

Hypersensitivity

Hypersensitivity and allergic reactions have occurred after the first administration. The doctor should be informed immediately.

Anaphylactic/anaphylactoid reactions can progress to a life threatening shock. Ciprofloxacin should be discontinued in these cases and appropriate medical treatment started.

Injection Site Reaction

Local I.V. site reactions have been reported with the intravenous administration of Ciprofloxacin. These reactions occur more frequently if the infusion time is 30 minutes or less. They 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.

Musculo-Skeletal System

At any sign of tendonitis, e.g. the administration of Ciprofloxacin should be discontinued, physical exercise avoided and a physician consulted. Tendon rupture (predominantly the Achilles tendon) has been reported predominantly in the elderly on prior systemic treatment with glucocorticoids.

Skin and Appendages

Ciprofloxacin can cause photosensitivity reactions. Patients should avoid direct exposure to excessive sunlight or UV-light. Therapy should be discontinued if photosensitisation occurs.

Hypoglycaemia

Hypoglycaemia has been noted with enoxacin lomefloxacin but it is not known whether it occurs with Ciprofloxacin.

Sodium Load

The additional sodium load should be taken into account when using Ciprofloxacin Infusion in patients where sodium intake is restricted e.g. patients with congestive heart failure, renal failure, nephritic syndrome. Each 100mL of Ciprofloxacin infusion contains 900mg of sodium chloride.

Use during Pregnancy and Lactation

Category B3
Ciprofloxacin must not be prescribed for pregnant women, or nursing mothers, since there is no experience on the drug's safety in these patient groups and since, on the basis of animal studies, it is possible that the drug could cause damage to articular cartilage in the foetus or infant. Animal studies have not shown any evidence of teratogenic effects (malformations).

Effects on ability to drive and use machines

Ciprofloxacin can affect the speed of reaction to such an extent that the ability to drive or operate machinery is impaired. This is particularly true when Ciprofloxacin is taken in combination with alcohol.

Adverse Effects

The most common adverse effects that have been observed during clinical studies and spontaneous reporting (both oral and parenteral) are as follows:

Digestive System

Incidence $\geq 1\%$ and $< 10\%$: nausea, diarrhoea

Incidence $\geq 0.1\%$ and $< 1\%$: SGOT increased, SGPT increased, vomiting, dyspepsia, abnormal liver function test, alkaline phosphatase increased, anorexia, flatulence, bilirubinemia

Incidence $\geq 0.01\%$ and $< 0.1\%$: moniliasis (oral), jaundice, cholestatic jaundice, pseudomembranous colitis

Incidence $< 0.01\%$: moniliasis (gastrointestinal), hepatitis, liver necrosis (very rarely progressing to life-threatening hepatic failure), life threatening pseudomembranous colitis with possible fatal outcome.

Skin and Appendages

Incidence $\geq 1\%$ and $< 10\%$: rash

Incidence $\geq 0.1\%$ and $< 1\%$: pruritus, maculopapular rash, urticaria

Incidence $\geq 0.01\%$ and $< 0.1\%$: photosensitivity reaction

Incidence $< 0.01\%$: petechiae, erythema multiforme (minor), erythema nodosum, fixed eruption, Stevens-Johnson-Syndrome, epidermal necrolysis (Lyell-Syndrome)

Body as a Whole

Incidence $\geq 0.1\%$ and $< 1\%$: abdominal pain, moniliasis, asthenia (general feeling of weakness, tiredness)

Incidence $\geq 0.01\%$ and $< 0.1\%$: pain, pain in extremities, back pain, chest pain

Cardiovascular

Incidence $\geq 0.1\%$ and $< 1\%$: thrombophlebitis

Incidence $\geq 0.01\%$ and $< 0.1\%$: tachycardia, migraine, syncope (fainting), vasodilatation (hot flushes), hypotension

Incidence $< 0.01\%$: vasculitis (petechiae, haemorrhagic bullae, papules, crust formation)

Haemic and Lymphatic System

Incidence $\geq 0.1\%$ and $< 1\%$: eosinophilia, leucopenia

Incidence $\geq 0.01\%$ and $< 0.1\%$: anaemia, leucopenia (granulocytopenia), leucocytosis, altered prothrombin values, thrombocytopenia, thrombocytemia (thrombocytosis)

Incidence $< 0.01\%$: haemolytic anaemia, petechiae (punctuate skin haemorrhages), pancytopenia (life-threatening), bone marrow depression (life-threatening), agranulocytosis

Injection Site Reaction

Incidence $\geq 0.1\%$ and $< 1\%$: injection site reaction

Metabolic Disorders

Incidence $\geq 0.1\%$ and $< 1\%$: creatinine increased, BUN (urea) increased

Incidence $\geq 0.01\%$ and $< 0.1\%$: oedema (peripheral, vascular, face), hyperglycaemia

Musculo-Skeletal System

Incidence $\geq 0.1\%$ and $< 1\%$: arthralgia (joint pain)

Incidence $\geq 0.01\%$ and $< 0.1\%$: myalgia (muscular pain), joint disorder (joint swelling)

Incidence $< 0.01\%$: myasthenia, tendinitis (predominantly achillotendinitis); partial or complete tendon rupture (predominantly achilles tendon), exacerbation of symptoms of myasthenia gravis.

Nervous System

Incidence $\geq 0.1\%$ and $< 1\%$: headache, dizziness, insomnia, agitation, confusion

Incidence $\geq 0.01\%$ and $< 0.1\%$: hallucination, sweating, paresthesia (peripheral paralgesia), anxiety, abnormal dreams (nightmares), depression, tremor (trembling), convulsion, hypaesthesia

Incidence $< 0.01\%$: grand mal convulsion, abnormal (unsteady) gait, psychosis, intracranial hypertension, ataxia, hypertonia, twitching

Special Senses

Incidence $\geq 0.1\%$ and $< 1\%$: taste perversion

Incidence $\geq 0.01\%$ and $< 0.1\%$: tinnitus, transitory deafness (especially at high frequencies), abnormal vision (visual disturbances), diplopia, chromatopsia, taste loss (impaired taste)

Incidence $< 0.01\%$: parosmia (impaired smell) anosmia (usually reversible on discontinuation)

Hypersensitivity

Incidence $\geq 0.01\%$ and $< 0.1\%$: allergic reaction, drug fever, anaphylactoid (anaphylactic) reaction

Incidence $< 0.01\%$: shock (anaphylactic; life threatening), pruritic rash, serum sickness like reaction

Respiratory System

Incidence $\geq 0.01\%$ and $< 0.1\%$: dyspnea, larynx oedema

Urogenital System

Incidence $\geq 0.01\%$ and $< 0.1\%$: acute kidney failure, kidney function abnormal, vaginal moniliasis, haematuria, crystalluria, nephritis interstitial

Interactions

Concurrent administration of ciprofloxacin and theophylline can cause an increase in the serum theophylline concentration. This can result in theophylline induced side effects which in rare cases may be life threatening or fatal. If concurrent use of the two products is unavoidable, the serum theophylline concentration should be monitored and the theophylline dose reduced as appropriate.

Animal studies have shown that the combinations of very high doses of quinolones (gyrase inhibitors) and some NSAIDs (not acetylsalicylic acid) can cause convulsions.

A transient rise in serum creatinine concentration was observed when Ciprofloxacin and cyclosporin were administered simultaneously. Serum creatinine concentrations should be monitored twice weekly in these patients.

The simultaneous administration of Ciprofloxacin and warfarin may intensify the action of warfarin.

Concurrent administration of Ciprofloxacin and glibenclamide may cause hypoglycaemia.

Probenicid interferes with the renal secretion of Ciprofloxacin. Co-administration of probenicid and Ciprofloxacin increases Ciprofloxacin serum concentrations.

Renal tubular transport of methotrexate may be inhibited by concomitant administration of Ciprofloxacin potentially leading to increased plasma levels of methotrexate. This may increase the risk of methotrexate associated toxic reactions. Patients receiving methotrexate therapy should be carefully monitored when concomitant ciprofloxacin therapy is indicated.

Tizanidine serum concentrations increase with concomitant administration of Ciprofloxacin with an associated potentiated hypotensive and sedative effect. Tizanidine must not be administered together with Ciprofloxacin.

Overdosage

In addition to normal emergency measures, it is recommended that renal function be monitored.

Less than 10% of Ciprofloxacin is removed from the body after haemodialysis or peritoneal dialysis.

Pharmaceutical Precautions

Storage

Store below 30°C. Protect from heat, light and moisture. Do not freeze.

The product should not be stored in a refrigerator as precipitation which will re-dissolve at room temperature, may occur at cool storage temperatures.

The infusion solution is photosensitive therefore the product should only be removed from the carton immediately before use.

Incompatibilities

If compatibility with other infusible solutions or medication has not been established, ciprofloxacin must be administered separately. Visible incompatibility indicators are sedimentation, turbidity and discolouration.

Incompatibility appears with all infusion solutions/drugs that are physically or chemically unstable at the pH of the solution e.g. penicillins and heparin solutions, especially in combination with solutions adjusted to an alkaline pH. The pH of the ciprofloxacin solution is 3.9-4.5.

Compatible solutions are physiological saline, Ringer solution and Ringer lactate solution, 5% and 10% dextrose solutions, 10% fructose solution and 5% dextrose solution with 0.225% or 0.45% sodium chloride. When ciprofloxacin infusion solutions are mixed with compatible infusion solutions they should be administered shortly after mixing for microbiological and light sensitivity reasons.

Medicines Classification

Prescription Medicine

Package Quantities

50mL: Packs of 1 vial which are packed into a carton of 6 packs
100mL and 200mL: Packs of 1 vial.

Further Information

Product also contains Lactic acid, Sodium hydrochloride, Hydrochloric acid and Water for Injection.

Name and Address

AFT Pharmaceuticals Ltd
PO Box 33-203
Takapuna
Auckland
Email: customer.service@aftpharm.com

Date of Preparation

15 July 2008