Insert

Actual Size

4

PREGNANCY AND LACTATION

As information from well controlled studies in pregnant women is not available and Since Ciprofloxacin causes arthropathy in immature animals, it should not be used in pregnant and nursing women.

DRUG INTERACTIONS

Serum concentrations and elimination half-life of theophylline may be increased when it is used concurrently with Ciprofloxacin. It is recommended that patients be monitored for the signs of theophylline toxicity during concurrent use and dosage adjustments made as appropriate. Probenecid delays excretion of Ciprofloxacin.

ADVERSE REACTIONS

Ciprofloxacin is generally well tolerated. During clinical trials in a large number of patients, adversely effects related to drug occurred infrequently and were commonly reported as diarrhoea, abdominal pain, headache, restlessness and rash.

Other side effects which have been reported very rarely include arthralgia and increased in serum transaminases levels.

On I.V. administration, local irritation at the site of injection and thrombophlebitis may occur.

OVERDOSAGE

In the case of overdosage, gastric lavage, adequate hydration, haemodialysis or peritoneal dialysis is recommended.

IMPORTANT

Not recommended for children, adolescent, during pregnancy and breast feeding mothers.

CAUTION

Not to be used if container is found leaking or solution is not clear. Solutions containing visible solid particles must not be used.

PRESENTATION

FFS Bottle of 100 ml.

STORAGE

Store at a temperature not exceeding 30°C. Protect from light. Do not freeze.

Mfg. Lic. No. : G/LVP/1

Manufactured by :

Amanta

Amanta Healthcare Ltd.
Plot No. 876, N.H.No. 8, Hariyala,
Kheda - 387411, Gujarat, India.

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For the use of Registered Medical Practitioner or a Hospital or a Laboratory only.

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CIPROFLOXACIN INJECTION USP (0.2% w/v)

For Intravenous Administration Only

Each 100 ml contains :

Ciprofloxacin Hydrochloride eq. to
Ciprofloxacin USP.....200 mg.
Sodium Chloride USP.....0.9% w/v
Water For Injection USP.....Q.S.

PHARMACOLOGY

Mechanism of Action

Ciprofloxacin is a bactericidal agent. The rapid bactericidal action of ciprofloxacin is attributed to its unique mode of action. It interacts with both, A and B subunits of DNA gyrase and disrupts the DNA function leading to death of bacteria. Bacterial resistance with Ciprofloxacin is extremely low. Ciprofloxacin eliminates plasma mediated resistance.

Antimicrobial Activity

Ciprofloxacin has most potent invitro antibacterial activity against most bacteria. Ciprofloxacin has MIC 90 < 1mg/L indicating susceptibility against all species.

Ciprofloxacin is active against a wide range of Gram positive and Gram negative pathogens including strains resistant to Penicillin's, Cephalosporins and/or Aminoglycosides.

Ciprofloxacin is effective against both replicating strains and those in the stationery phase. It is also effective against intracellular bacteria. It has significant post-antibiotic effect and thus prevents regrowth of bacteria. There is no plasmid mediated resistance and it does not show any cross resistance with other antibiotics or antibacterial agents.

Ciprofloxacin has an antibacterial spectrum which is wider than the spectrum of aminoglycosides, third generation cephalosporins and other fluoroquinolones

Ciprofloxacin spectrum includes the following organisms.

a) **Gram negative bacteria**

Enterobacteriaceae : E. coli, Klebsiella species, Proteus species, Enterobacter species, Morganella morganii, Citrobacter species, Serratia species & Providencia species.

Pseudomonadaceae : Ps. aeruginosa and Ps. cepacia.

Enteropathogens : Salmonella species, Shigella species, Enteropathogenic E. coli, Y. enterocolitica, A. hydrophilia, V. Cholerae, Campylobacter jejuni & Arizona species.

Miscellaneous : N. gonorrhea, N. meningitidis, H. influenzae, Acinetobacter anitratus, Branhamella Catarrhalis, Pasteurella, Moraxella & Gardnerella vaginalis.

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b) **Gram positive bacteria**

Staph. aureus including penicillinase-producing and methicillin resistant strains; Staph. epidermidis, Strep. pyogenes, Strep. agalactiae, Strep. pneumoniae, Strep. viridans and Listeria moncytogenes.

c) **Intra-cellular bacteria-resistant strains**

Chlamydia trachomatis, Mycoplasma hominis, Legionella species, Brucella species; Anaerobes including most species of Bacteriodes; Clostridium and Fusobacterium.

PHARMACOKINETICS

Ciprofloxacin has favourable pharmacokinetics for systemic use. The mean peak serum concentrations following single doses of 100, 150 and 200 mg I.V. were 1.4, 2.0 and 3.2 mg/Litre respectively. The terminal half life averaged between 4.2 and 4.6 hours. The distribution and tissue penetration of Ciprofloxacin is extremely good and the drug reaches therapeutic concentrations in most body tissues and fluids including sputum, bone, peritoneal fluid, prostrate and pelvic tissues. Average urinary recovery ranged between 45.8 and 48.1%. The protein binding of Ciprofloxacin is low. Significant amounts are also excreted in bile and faeces. Upto 70% of a parenteral dose may be excreted unchanged within 24 hours and 10% as metabolites through urine. Faecal excretion over 5 days has accounted for 15% of an intravenous dose.

INDICATIONS

Ciprofloxacin is indicated for the treatment of a wide variety of susceptible Gram-positive and Gram-negative organisms including mixed infections caused by two or more organisms. It may also be used for infections caused by multi-drug resistant bacteria. It can be used for :

Respiratory Tract Infections : Acute bronchitis, exacerbation of chronic obstructive airways disease, pneumonia, cystic fibrosis, lung abscess and infected bronchiectasis.

Urinary Tract Infections : Acute and chronic pyelonephritis, prostatitis, cystitis, epidymitis and chronic complicated or recurrent UTI caused by multi-resistant organisms and/or Pseudomonas aeruginosa.

Skin and Soft Tissue Infections : In surgical and post operative wound infections due to Gram-negative organisms such as Enterobactericeae and Pseudomonas aeruginosa. Also useful in infections caused by resistant Staphylococci. e.g. infected ulcer, cellulitis, otitis externa, infected burns etc.

Gynecological Infections : Severe pelvic infections caused by susceptible bacteria (e.g. Salpingitis, Endometritis, etc.)

Sexually Transmitted Diseases : Gonorrhea including that caused by susceptible beta-lactamase producing strains, Chancroid caused by H. ducreyi.

Bone and Joint Infections : Ciprofloxacin achieves adequate tissue concentrations in bone, it is useful in the management of acute and chronic osteomyelitis & septic arthritis.

Gastrointestinal Infections : Ciprofloxacin is highly effective in the treatment of typhoid and may also eradicate carrier stage. It is useful in resistant Salmonella infections & infective diarrhoea.

Surgical Infections : Peritonitis, Intra-abdominal abscess, cholongitis, cholestitis, empyema of gall bladder.

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Severe Systemic Infections : Septicemia, bacteremia infections in immunocompromised patients.

E.N.T. Infections : Otitis media, Sinusitis, Mastoditis, Tonsilitis.

DOSAGE

Usual recommended I.V. dosage is as follows :

In *Adults*

Respiratory Tract Infections	:	200 mg twice daily by slow I.V. infusion
Gonorrhea	:	A single dose of 100 mg I.V. infusion.
In majority of other infections	:	200 mg should be administered by slow I.V. infusion every 12 hours daily.

The total daily dose should be halved in patients with severe renal impairment (Creatinine clearance < 20 ml/min.)

In *Children*

Ciprofloxacin is usually not recommended for use in children. However, if the benefits of Ciprofloxacin therapy are considered to outweigh the potential risk, the dosage should be 5 to 10 mg/Kg/day in two divided doses, depending upon the severity of infections.

ADMINISTRATION

Ciprofloxacin infusion in 100 ml. (200 mg) infusion bottle may be infused directly and should be administered by short term infusion over a period of 30 - 60 minutes.

DURATION OF TREATMENT

The usual duration of therapy for acute infections is 5 to 7 days. generally, therapy should be continued for at least 3 days after the signs and symptoms of the infection have disappeared. In some infections long term therapy has been given.

Initial intravenous administration may be followed by oral Ciprofloxacin, whenever required.

CONTRAINDICATIONS

Ciprofloxacin is contraindicated in hypersensitive patients. Its use is not recommended in children below the age of 12 years.

PRECAUTIONS

As Ciprofloxacin may cause CNS stimulation, it should be used with caution in patients with CNS disorders such as epilepsy.

Patients receiving this drug should be well hydrated to prevent crystalluria.

The dosage of Ciprofloxacin in patients with renal impairment should be reduced to half if creatinine clearance is less than 20 ml/min.

Antacids containing Magnesium hydroxide and/or aluminium hydroxide may interfere with the absorption of Ciprofloxacin, resulting in lower serum and urine levels, concurrent administration of antacids with Ciprofloxacin should be avoided.

Reproduction studies in animal at doses up to 6 times the usual daily human dose have not revealed any evidence of teratogenicity or impaired fertility due to Ciprofloxacin.

145 mm

95 mm

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