CIPROFAR Tablets (Film Coated)

Broad Spectrum Quinolone Antibiotic

Composition : Each tablet contains

Ciprofloxacin hydrochloride monohydrate: equivalent to 250 mg, 500 mg or 750 mg ciprofloxacin.

Properties

Ciprofar (ciprofloxacin) is a highly effective broad spectrum antihacterial agent belonging to fluoroquinolones. Ciprofar is bactericidal against a wide range of Gram-negative and Gram-positive bacteria including strains resistant to aminoglycosides, beta-lactams and other commonly used antibiotics. Ciprofar acts through selective inhibition of the A subunit of DNA gyrase (topoisomerase) with subsequent prevention of DNA replication and rapid bacterial cell death. Ciprofar possesses favorable pharmacokinetic properties that ensure complete eradication of invading pathogens from almost all body tissues and fluids. Clinically, Ciprofar therapy gives rise to an almost complete cure rate even in cases caused by multiple antibiotic-resistant organisms. These properties, besides excellent tolerability and patient compliance, make Ciprofar the most reliable and effective guinolone antibiotic for treatment of a wide range of local and systemic infections.

Pharmacokinetics
Ciprofloxacin is rapidly and well absorbed from the GIT. Peak plasma concentrations are achieved within 1-2 hours. Plasma protein binding ranges from 20-40%. Ciprofloxacin is widely distributed throughout body fluids and tissues. At recommended doses, concentrations several times greater than the minimum inhibitory concentration (MIC) are achieved in urine prostate and other genital tissues, bile, bone, respiratory secretions and skin. A large part of

the drug is excreted unchanged (50% in urine and 20-35% in feces). The remaining part undergoes hepatic biotransformation into metabolites which are excreted in the urine and feces. The plasma half-life is about 4 hours Ciprofloxacin crosses the placenta and is excreted in breast milk Antimicrobial Spectrum Ciprofar is bactericidal against a wide range of aerobic and facultative

anaerobic microorganisms: Gram-negative bacteria: Escherichia coli, Gardnerella vaginalis, Haemophilus ducreyi, H. influenzae, parainfluenzae, Helicobacter pylori, Moraxella catarrhalis, Neisseria gonorrhoeae, N. meningilidis, Pseudomonas aeruginosa, Acinetobacter, Campylobacter, Citrobacter, Enterobacter, Klebsiella, Legionella, Proteus, Providencia, Salmonella, Serratia, Shigella, Vibrio, Yersinia species,

Pasteurella multocida, Brucella melitensis and Morganella morganii. Gram-positive bacteria: Staphylococcus aureus (including penicillin-resistant strains). Stanh epidermidis, Streptococcus pyogenes, S. pneumoniae, S. faecalis, Listeria

monocytogenes. Corynebacterium species and B. anthracis. Miscellaneous microorganisms: Chlamydiae, Mycobacteria, Mycoplasmas, Rickettsiae and the protozoan

Plasmodium faloiparum. Indications Ciprofar is indicated for treatment of infections caused by ciprofloxacin-

suscentible organisms . Urinary tract infections : pyelonephritis , cystitis and urethritis including complicated and uncomplicated conditions

· Genital tract infections: prostatitis, epididymitis, epididymo-orchitis, salpingitis and salpingo-cophoritis. . Venereal diseases: urethral and cervical gonorrhea, nonponococcal urethritis

and chancroid · Gastrointestinal tract infections : infectious diarrhea, ententis, enterocolitis and enteric (typhoid and paratyphoid) fevers

. Riliary tract infections: cholecystitis, cholangitis and choledochitis, . Bone and joint infections: osteomyelitis, bone abscess and septic arthritis. · Respiratory tract infections: pneumonia, bronchopneumonia, lung abscess, bronchiectasis, bronchitis and tracheobronchitis.

. ENT infections: otitis media, sinusitis, tonsillitis, laryngitis and pharyngitis.

 Skin and soft tissue infections: cellulitis, erysipelas, abscesses, carbuncles, pyodermia, impetigo, infected ulcers, animal bites and stings, infected traumatic and postoperative wounds. Miscellaneous Infections: peritonitis, spotted fever, typhus, Q fever and hypothesis. brucellosis and anthrax.

 Meningococcal meningitis (as a prophylactic agent). Dosage

· Urinary tract infections: skin and soft tissue infections :

mg tablet) as a single dose. Dosage in repail in

Mild to moderate: 250 mg (1 Ciprofar 250 mg tablet) every 12 hours.

Severe or complicated: 500 mg (1 Ciprofar 500 mg tablet) every 12 hours. Gastrointestinal and billary tract, bone and joint, respiratory tract, ENT,

- Mild to moderate: 500 mg (1 Ciprofar 500 mg tablet) every 12 hours.
- Mild to moderate: 500 mg (1 Ciprofar 750 mg tablet) every 12 hours.
- Severe or complicated: 750 mg (1 Ciprofar 750 mg tablet) severy 12 hours.
- Gonorrhea: 250 - 500 mg (1 Ciprofar 250 500 mg tablet) as a single dose. Meningococcal meningitis (prophylaxis): 500-750 mg (1 Ciprofar 500-750 mg (1 Ciprofar

Creatinine clearance	Creatinine clearance	Creatinine clearance
> 50 ml/min.	30 - 50 ml/min.	< 30 ml/min.
No change in dosage	250 - 500 mg every 12 hours	250 - 500 mg every 18 hours. • Patients under dialysis 250 - 500 mg every 24 hours after dialysis.

Contraindications Hypersensitivity to flouroquinolones. Fluoroquinolones are not generally recommended in children and adolescents (under 18 years).

As with other fluoroquinolones, ciprofloxacin should be given cautiously to patients with central neurological disorders, e.g. epilepsy, and also to patients with impaired renal or hepatic function. Prolonged exposure to direct sunlight

Side Effects Ciprofar is well tolerated. However, mild gastrointestinal disturbances, skin rash, pruntus, headache and dizziness rarely occur,

Pregnancy and Lactation Fluoroguinolones are not recommended during pregnancy and lactation.

Drug Interactions

Antacids containing aluminium, magnesium or calcium reduce ciprofloxacin absorption when taken concomitantly or within 2 hours of ciprofloxacin administration. Cip-

rofloxacin may enhance the effect of oral anticoagulants, theophylline and caffeine Interference with Laboratory Tests

should be avoided during therapy.

None reported. Overdosage and Treatment In case of accidental ingestion of

overdose, empty the stomach by inducing vomiting or gastric lavage and maintain adequate hydration with symptomatic treatment. Packing: A box containing 10 or 12 tablets

(250, 500 or 750 mg). Storage:

Keep at temperature (15 - 30° C), away from light Keep out of the reach of children.

THIS IS A MEDICAMENT Medicament is a product which af-

fects your health and its consumption contrary to instructions is dangerous Follow strictly the doctor's prescription, the method of use and instructions of the pharmacist who sold the

medicament - The doctor and the pharmacist are the experts in medicines, their benefits and risks. - Do not by yourself interrupt the peri-

od of treatment prescribed. - Do not repeat the same prescription without consulting your doctor. - Keep all medicaments out of reach

of children Council of Arab Health Ministers. Union of Arab Pharmacists.

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