Beuflox®

Ciprofloxacin tablet & granules for suspension

Presentation

Beuflox® 250: Each film-coated tablet contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 250 mg.
Beuflox® 500: Each film-coated tablet contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 500 mg.
Beuflox® 750: Each film-coated tablet contains Ciprofloxacin Hydrochloride USP equivalent to Ciprofloxacin 750 mg.
Beuflox® 250 Granules for suspension: Each sachet contains Ciprofloxacin USP 250 mg.
Beuflox® 125 Granules for suspension: Each sachet contains Ciprofloxacin USP 125 mg.
Beuflox® Granules for suspension 60 ml: Each 5 ml contains Ciprofloxacin USP 250 mg.

Description

Ciprofloxacin is a synthetic 4-quinolone derivative with bactericidal activity against a wide range of gram-positive and gram-negative organism. It is active against most gram-negative aerobic bacteria including *Enterobacteriaceae* and *Pseudomonas aeruginosa*. Ciprofloxacin is also active against gram-positive aerobic bacteria including penicillinase producing, non-penicillinase producing and methicillin resistant *Staphylococci*. However many strains of *Streptococci* are relatively resistant to the drug. The bactericidal activity of Ciprofloxacin results from interference with the enzyme DNA gyrase needed for the synthesis of bacterial DNA. The mode of action of Ciprofloxacin is different from other antibiotics like penicillins, cephalosporins, aminoglycosides, tetracyclines and for this reason it is observed that organisms resistant to these antibiotics are susceptible to Ciprofloxacin. Ciprofloxacin is well absorbed from the GIT after oral administration and it is widely distributed into the body tissues and fluid. The half-life of Ciprofloxacin is 3.5 - 4.5 hours. About 30-50% of an oral dose of Ciprofloxacin is excreted in the urine within 24 hours as unchanged drug and active metabolites.

Indications

Ciprofloxacin is indicated for the treatment of the following infections caused by sensitive bacteria:
Severe systemic infections: e.g; septicemia, bacteremia, peritonitis, infections in immunosuppressed patients with haematological or solid tumors and in patients in intensive care unit with specific problems such as infected burns.
Respiratory tract infections: Lobar and broncho pneumonia, acute and chronic bronchitis and empyema.
Urinary tract infections: Uncomplicated and complicated urethritis, cystitis, pyelonephritis, prostatitis and epididymitis.
Skin and soft tissue infections: Infected ulcers, wound infections, abscesses, cellulitis, otitis externa, erysipelas and infected burns.
Gastrointestinal infections: Enteric fever, infective diarrhea.
Infections of the biliary tract: Cholangitis, cholecystitis, empyema of the gall bladder.
Intra-abdominal infections: Peritonitis, intra abdominal abscesses.
Bone and joint infections: Osteomyelitis, septic arthritis.
Pelvic infections: Salpingitis, endometritis, pelvic inflammatory diseases.
Eye, ear, nose and throat infections: Otitis media, sinusitis, mastoiditis, tonsillitis.
Gonorrhoea: Urethral, rectal and pharyngeal gonorrhoea caused by beta-lactamase producing organism or organisms moderately sensitive to penicillin.

Dosage and Administration

Adult :

Infection	*Severity*	*Dose*	*Frequency*	*Duration*
Urinary Tract	Acute uncomplicated	250 mg	12 h	3 days
	Mild/Moderate	250 mg	12h	7 to 14 days
	Severe/Complicated	500 mg	12 h	7 to 14 days
Chronic Bacterial Prostitis	Mild/Moderate	500 mg	12 h	28 days
Lower Respiratory Tract	Mild/Moderate	500 mg	12 h	7 to 14 days
	Severe/Complicated	750 mg	12 h	7 to 14 days
Acute Sinusitis	Mild/Moderate	500 mg	12 h	10 days
Skin and Skin Structure	Mild/Moderate	500 mg	12 h	7 to 14 days
	Severe/Complicated	750 mg	12 h	7 to 14 days
Bone and joint	Mild/Moderate	500 mg	12 h	> 4 to 6 weeks
	Severe/Complicated	750 mg	12 h	> 4 to 6 weeks
Intra Abdominal*	Complicated	500 mg	12 h	7 to 14 days
Infectious Diarrhea	Mild/Moderate/Severe	500 mg	12 h	5 to 7 days
Typhoid Fever	Mild/Moderate	500 mg	12 h	10 days
Urethral & Cervical Gonococcal Infections	Uncomplicated	250 mg	Single dose	Single dose

* use in conjunction with metronidazole

Children and adolescents:

RTI & GI infections: Neonate-15mg/kg twice daily, Child (1 month -18 years)-20mg/kg (max 750 mg) twice daily; UTI: Neonate-10 mg/kg twice daily, Child (1 month -18 years)-10mg/kg (max 750 mg) twice daily; Pseudomonal lower respiratory tract infection in cystic fibrosis: Child (1 month -18 years) - 20mg/kg (max 750 mg) twice daily; Anthrax (treatment & post exposure prophylaxis): Child (1 month -18 years) - 20mg/kg (max 750 mg) twice daily.

Use in Pregnancy and Lactation

Reproduction studies performed in rats and rabbits using parenteral and oral administration did not reveal any evidence of teratogenicity, impairment of fertility or impairment of pre or postnatal development. However, as with other quinolones, Ciprofloxacin has been shown to cause arthropathy in immature animals and therefore, its use during pregnancy is not recommended. Studies in rats have indicated that Ciprofloxacin is secreted in milk, administration to nursing mothers is thus not recommended.

Side effects

Ciprofloxacin is generally well tolerated. Frequent adverse reactions are- *Gastrointestinal disturbance:* e.g. nausea diarrhea, vomiting, dyspepsia, abdominal pain. *Disturbance of the CNS:* e.g. dizziness, headache, tiredness, confusion, convulsions. *Hypersensitivity reactions:* e.g. skin rashes, pruritus, and possible systemic reactions. Other possible side effects are - joint pain, light sensitivity, transient increase in liver enzyme (especially in patients with history of liver damage), serum bilirubin, urea or serum creatinine. Arthralgia and myalgia may also occur.

Contraindications

Ciprofloxacin is contraindicated in patients who have hypersensitivity to Ciprofloxacin or other quinolones.

Precautions

Ciprofloxacin should be used with caution in patients with a history of convulsive disorders. Crystalluria related to the use of Ciprofloxacin has been observed only rarely. Patients receiving Ciprofloxacin should be well hydrated to avoid excessive alkalinity of the urine.

Drug interactions

Concurrent administration of Ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline. Plasma level of theophylline should be monitored and dosage adjustments made as appropriate. Antacid containing magnesium hydroxide or aluminium hydroxide may interfere with the absorption of Ciprofloxacin & concurrent administration of these agents with Ciprofloxacin should be avoided. Probenecid interferes with renal tubular secretion of Ciprofloxacin and produces an increase in the level of Ciprofloxacin in the serum. As with other broad spectrum antibiotics prolonged use of Ciprofloxacin may result in over growth of non-susceptible organisms. Repeated evaluation of patient's conditions and microbial susceptibility testing is essential. If superinfections occur during therapy, appropriate measure should be taken.

Information for patients

Beuflox should be swallowed whole with an adequate amount of liquid, it may be taken with or without meals. The preferred time of dosing is two hours after a meal and patients should not take antacid within two hours of dosing.

Directions for use of granules for suspension

Whole contents of the packet should be taken into a small glass containing 2-3 teaspoonful of water. Other liquids or foods should not be used. The mixer should be stirred well and drink immediately. The glass should be refilled with water and drink.

Direction for reconstitution of suspension (60 ml)

Shake the bottle well to loosen the granules. Add 50 ml (with the help of supplied measuring cup) of boiled cool water to the dry granules in the bottle. Shake the bottle vigorously until all the granules is in suspension.

Commercial pack

Beuflox® 250: Box containing 6 blister strips of 3 film coated tablet.
Beuflox® 500: Box containing 2 blister strips of 10 film coated tablet.
Beuflox® 750: Box containing 2 blister strips of 10 film coated tablet.
Beuflox® 250 granules for suspension: Each box contains 14 sachets.
Beuflox® 125 granules for suspension: Each box contains 14 sachets.
Beuflox® Granules for suspension 60 ml: Each glass bottle contains Granules for preparing 60 ml suspension.

V.N.02

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