

CERO

Ciprofloxacin Tablet

COMPOSITION:

CERO-250 Tablet : Each film coated tablet contains Ciprofloxacin Hydrochloride B.P. equivalent to 250 mg of Ciprofloxacin.

CERO-500 Tablet : Each film coated tablet contains Ciprofloxacin Hydrochloride B.P. equivalent to 500 mg of Ciprofloxacin.

CERO-750 Tablet : Each film coated tablet contains Ciprofloxacin Hydrochloride B.P. equivalent to 750 mg of Ciprofloxacin.

DESCRIPTION: Ciprofloxacin is a synthetic, 4-quinolone derivative with bactericidal activity against a wide range of Gram-negative and Gram-positive organisms.

MICROBIOLOGY: Invitro studies have shown that the antibacterial action of Ciprofloxacin results from inhibition of bacterial DNA gyrase. This mode of action differs from that of penicillins, cephalosporins, aminoglycosides and tetracycline and therefore, organisms resistant to these antibiotics are generally sensitive to Ciprofloxacin.

INDICATIONS: Ciprofloxacin is indicated for the treatment of single infection or mixed infections caused by two or more susceptible organisms. It may be used for infections caused by organisms resistant to other antibiotics, including aminoglycosides, penicillin and cephalosporins. Ciprofloxacin is indicated for the treatment of the following infections caused by sensitive bacteria. Severe systemic infections: Septicemia, bacteremia, peritonitis, infections in immunosuppressed patients with hematological or solid tumors and in patients in intensive care units with specific problems such as infected burns.

RESPIRATORY TRACT INFECTIONS: Lobar and bronchopneumonia, acute and chronic bronchitis, acute exacerbation of cystic fibrosis, bronchiectasis, empyema.

EAR, NOSE AND THROAT INFECTIONS: Otitis media, sinusitis and mastoiditis especially if due to Gram-negative bacteria (including pseudomonas spp).

URINARY TRACT INFECTIONS: Uncomplicated arthritis, cystitis, pyelonephritis, prostatitis, epididymitis.

SKIN AND SOFT TISSUE INFECTIONS: Infected ulcer, wound infections, abscesses, cellulose, otitis externa, erysipelas, infected burns.

GASTROINTESTINAL INFECTIONS: Enteric fever, ineffective diarrhoea,

BONE JOINT INFECTIONS: Osteomyelitis, Septic arthritis.

PELVIC INFECTIONS: Salpingitis, Pelvic inflammatory disease.

GONORRHOEA: Urethral, rectal and pharyngeal gonorrhea caused by betalactamase producing organisms or organisms moderately sensitive to penicillin.

CONTRAINDICATION: Ciprofloxacin is contraindicated in patients who have shown hypersensitivity to Ciprofloxacin or other quinolones. It is also contraindicated in children and growing adolescents except where the benefits of treatment outweigh the risk.

DOSAGE AND ADMINISTRATION: The usual adult oral dose of Ciprofloxacin ranges from 250 to 750 mg twice daily depending on the severity and nature of the infection.

Single oral doses of 250 or 500 mg are used for the treatment of gonorrhoea, depending upon patterns of resistance. A single oral dose of 500 mg is suggested for meningococcal meningitis prophylaxis. A single oral dose of 750 mg is suggested for surgical infection prophylaxis, given 60 to 90 minutes between the procedure. Ciprofloxacin may be given to adolescents and children used 5 years on more in a dose of 20 mg per kg by mouth twice daily, up to a maximum of 750 mg twice daily.

ADOLESCENTS AND CHILDREN: The use of Ciprofloxacin is not recommended for the growing adolescents and children. However it is used when potential benefit is considered to outweigh this potential risk of the product. The dose should be 7.5 mg to 15 mg/kg/day (oral) in two divided doses, depending of the severity of infection. Duration of treatment: For acute infections the usual treatment period is 5 to 10 days. Generally, In acute and chronic infection treatment should be continued for at least 3 days after the signs and symptoms of the infection have disappeared.

PRECAUTIONS: Ciprofloxacin should be used with caution in epilepsy and patients with a history of CNS disorders. Ciprofloxacin impairs patients ability to drive or operate machinery particularly if conjunction with alcohol. Crystalluria related to the use of Ciprofloxacin has been reported. Patients receiving Ciprofloxacin should be used with caution in hepatic and renal impairment.

DRUG INTERACTION: Ciprofloxacin should not be taken with 4 hours of medications containing magnesium, aluminium, calcium or iron salts as interference with absorption may occur. Increased plasma levels of theophylline have been observed when administration concurrently with Ciprofloxacin. Prolongation of bleeding time has been reported during concomitant administration of Ciprofloxacin and oral anticoagulants.

USE IN PREGNANCY AND LACTATION: As Ciprofloxacin has been shown to cause arthropathy in immature animals and therefore its use during pregnancy is not recommended. Ciprofloxacin is secreted in breast milk, administration of Ciprofloxacin is thus not recommended to nursing mothers.

SIDE EFFECTS: Ciprofloxacin is generally well tolerated. The most frequently reported adverse reactions are nausea, diarrhoea, vomiting, dyspepsia, abdominal pain, headache, restlessness rash, dizziness and pruritus. The following adverse reaction have been observed: confusion, hallucination, somnolence, tremor, urticaria, photosensitivity, anaphylaxis, blurred vision, transient increase in liver enzyme or serum bilirubin, hepatitis, jaundice, crystalluria, nephritis, arthralgia, myalgia, blood disorders including eosinophilia, thrombocytopenia, thrombocytosis, pseudomembranous colitis vasculitis. Stevens Johnson Syndrome and tachycardia.

OVERDOSE: No information on overdose is available. Routine measures such as gastric lavage should be performed as soon as possible after ingestion of Ciprofloxacin tablets. Serum level of Ciprofloxacin are reduced by dialysis.

PHARMACEUTICAL PRECAUTIONS: Store at room temperature, protected from light and moisture. Keep away from Children.

STORAGE: No special precaution are necessary for Ciprofloxacin tablets.

PACKING:

Cero-250 Tablet: Box Containing 1x10's Tablets in blister pack.

Cero-500 Tablet: Box Containing 1x10's Tablets in blister pack.

Cero-750 Tablet: Box Containing 1x10's Tablets in blister pack.

Manufactured by:

Gaeo Pharmaceuticals
(G. A. Company Ltd.)
Dhaka, Bangladesh