Cipotent
(Ciprofloxacin)

سِپوٹینٹ
(سپروفلاکساسین)

250mg & 500mg Tablets
125mg/5ml & 250mg/5ml Suspension

Cipotent 250mg Tablet
Composition:
Each film coated tablet contains:
Ciprofloxacin HCl equivalent
to Ciprofloxacin ..... 250 mg

Cipotent 500mg Tablet
Composition:
Each film coated tablet contains:
Ciprofloxacin HCl equivalent
to Ciprofloxacin ..... 500 mg

Cipotent 125mg/5ml Suspension
Composition:
When reconstituted as directed each 5ml contains:
Ciprofloxacin HCl equivalent to
Ciprofloxacin ..... 125 mg

Cipotent 250mg/5ml Suspension
Composition:
When reconstituted as directed each 5ml contains:
Ciprofloxacin HCl equivalent to
Ciprofloxacin ..... 250 mg

PROPERTIES:
CIPOTENT is a synthetic broad spectrum antibacterial agent for oral administration.

Microbiology:
CIPOTENT has invitro activity against a wide range of gram-positive and gram-negative organisms. The bactericidal activity of CIPOTENT results from interference with the enzyme DNA-gyrase which is needed for the synthesis of bacterial DNA.

Clinical Pharmacology:
CIPOTENT tablets are rapidly and well absorbed from the gastro-intestinal tract after oral administration. The absolute bioavailability is approximately 70% with no substantial loss of first pass metabolism. Maximum serum concentration are attained 1-2 hours after oral dosing. Mean concentrations 12 hours after dosing with 250mg and 500mg are 0.1 and 0.2 mcg/ml, respectively. The serum elimination half-life in subjects with normal renal functions is approximately 4 hours. CIPOTENT is available in high concentration in body fluids and tissue at bid dosing. Approximately 40-50% of an orally administered dose is excreted in the urine as unchanged drug. After a 250mg oral dose, urine concentration of Ciprofloxacin usually exceed 200 mcg/ml during the first two hours and are approximately 30 mcg/ml at 8 to 12 hours after dosing. The urinary excretion of Ciproxfloxacin is virtually complete within24 hours after dosing. Thus, active tubular secretion would seem to play a significant role in elimination.

Indications & Usage:
CIPOTENT is indicated for the treatment of infections caused by susceptible strains of the designated micro-organisms in the conditions listed below.
• Respiratory infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Haemophilus influenzae, Haemophilus parainfluenzae or streptococcus pneumoniae.
• Middle ear (otitis media) of the paranasal tissues (sinusitis), especially if these are caused by gram-negative organisms including Pseudomonas or by Staphylococcus.
• Urinary tract infections caused by E.coli, Klebsiella pneumoniae, Enterobacter cloacae, Serratia marcescens, Proteus mirabilis, Providentia rettgeri, Morganella morganii, Citrobactediversus, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus epidermis or Enterococcus faecalis.
• Skin and skin structure infections caused by Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Morganella organii, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus aureus, Stapylococcus epidermidis of Streptococcus pyogenes.
• Septicemia.
• Reproductive organs, including gonorrhoea.
• Bone and joint infections caused by Enterobacter cloacae, Serratia marcescens, or Pseudomonas aeruginosa.
• Abdominal cavity (eg. bacterial infections of the gastro-intestinal tract, billiary tract, peritonitis.
CIPOTENT has bactericidal action against most strains of the following organisms both in vitro and clinical infections. E. coli, Haemophilus influenzae, Klebsiella pneumonial, Morganellamorganii, Proteus

mirabilis, Proteus vulgaris, Provedencia rettgeri, Providentia stuartii, Pseudomonas aeruginosa, Serratia marcescens, Shigella typhi, Vibrio cholerae, Enterococcus faecalis, Staphylococcus aureus, Staphylococcus epidermidis.
Other organisms are sensitive in varying degree: Cliamydia trachomatis (only moderately susceptible), Cardnerella, Mycobacterium tuberculosis (only moderately susceptible);
Streptococcus faecalis, Streptococcus pyogenes, Streptococcus viridans. The following are generally resistant: Streptococcus faecium, Urea plasma, Urea lyticum, Nocardia asteriodes. Anaerobes; apart from a few exceptions, vary from being moderately sensitive (e.g. peptococcus,peptostreptococcus) to resistant to (e.g. bacteriodes). Invitro studies have shown that additive activity often results when Ciprofloxacin is combined with other antimicrobial agents such as beta-lactams, aminoglycosides, clindamycin or metronidazole, synergy has been reported particularly with the combinations of Ciprofloxacin and beta-lactams; antagonism is observed only rarely.

CONTRAINDICATIONS:
CIPOTENT (Ciprofloxacin hydrochloride) is contraindicated in persons with a history of hypersensitivity to Ciprofloxacin or any member of the quinolone class of antimicrobial agents.

WARNINGS:
The safety and effectiveness of Ciprofloxacin in children, adolescents (less than 18 years of age), pregnant women and lactating women have not been established. Fluoroquinolones including CIPOTENT, are associated with an increased risk of tendinitis and tendon rupture in all ages. Fluoroquinolones, including CIPOTENT, may exacerbate muscle weakness in persons with myasthenia gravis. Serious and fatal reactions have been reported in patients receiving concurrent administration of Ciprofloxacin and theophylline. Pseudom, embraneous colitis has been reported with nearly all antibacterial agents, including Ciprofloxacin and may range in severity from mild to life-threatening. Therefore it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial severe or persistant diarrhoea occurring during or after treatment, since these symptoms could conceal a serious intestinal disorder (pseudomembraneous colitis) requiring urgent treatment. In such cases CIPOTENT (Ciprofloxacin hydrochloride) should be discontinued and replaced by another appropriate drug (e.g. vancomycin orally 4x250mg/day). Preparations which inhibit peristalsis are contra-indicated.

Effects on nervous system:
Dizziness, lightheadedness, insomnia, drowsiness, weakness: very rarely: sweating, convulsions, unsteady gait, peripheral paralgesic, anxiety states, nightmares, confusion, depression, hallucinations, impaired taste and smell, visual disturbances (e.g. double vision, colour vision): In some instances, these reactions occurred after the first administration of Ciprofloxacin already. In these cases Ciprofloxacin has to be discontinued and the doctor should be informed immediately.

Hypersensitivity reactions:
Skin reactions e.g. rashes: very rarely: pruritis, drug fever. Allergic reactions varying from urticaria to anphylactic reactions have been reported.

Effect on cardiovascular system:
Very rarely tachycardia, hot flushes, migraine and fainting.

Effect on blood and blood constituents:
Eosinophillia, leucocytopenia, leucocytosis, anaemia: vary rarely: thrombocytopenia, thromobocytosis, altered prothrombin levels.

Effect on laboratory values/urine deposits:
There may be a transient rise in the transaminase and alkaline phosphatase levels, or cholestatic jaundice, may occur particularly in patients with previous liver damages transient increase in serum urea, creatinine and bilirubin levels, hyperglycaemia, in individual cases: crystalluria and haematuria.

Other Very rarely:
joint pains, general feeling of weakness, muscular pains, tendovaginitis, mild photosensitivity, transient impairment in kidney function, including transient kidney failure, tinnitus, transitory impairment of hearing, especially at high frequencies.

Warning to drivers:
Even when taken as prescribed, this drug can alter patients responsiveness, impairing the ability to drive or operate machinery. This is more applicable when the drug is taken in conjunction with alcohol.

INTERACTION:
Concurrent administration of Ciprofloxacin with theophylline may lead to elevated serum concentrations of theophylline and prolongation of its elimination half-life. This may result in increased risk of theophylline related adverse reactions. If concomitant use cannot be avoided, serum levels of theophylline should be monitored and dosage adjustments made as appropriate.
Concurrent administration of CIPOTENT with antacids containing magnesium, aluminium, or calcium with sucralfate or divalent and trivalent cations such as iron may substantially interfere with the absorption of Ciprofloxacin, resulting in serum and urine levels considerably lower than desired, Consequently, CIPOTENT should be taken either 1 -2 hours, or at least 4 hours after antacid. This restriction does not apply to antacids which do not contain aluminium or magnesium hydroxide (e.g. H2-receptor blockers). Animal experiments have indicated that the combination of very high doses of quinolones (gyrase inhibitors) with certain nonsteroidal anti-inflammatory drugs (e.g, fenbufen, but not acetylsalicylic acid) can lead to convulsions.

DOSAGE AND ADMINISTRATION PERIODS:
The usual dosage guidelines are as follows:

ADULT DOSAGE GUIDELINES

Infection	Severity	Dose	Frequency	Usual Duration
Urinary Tract	Acute Uncomplicated	250 mg	q 12 h	3 days
	Mild/Moderate	250 mg	q 12 h	7 to 14 days
	Severe/Complicated	500 mg	q 12 h	7 to 14 days
Chronic Bacterial Prostatitis	Mild/Moderate	500 mg	q 12 h	28 days
Lower Respiratory Tract	Mild/Moderate	500 mg	q 12 h	7 to 14 days
	Severe/Complicated	750 mg	q 12 h	7 to 14 days
Acute Sinusitis	Mild/Moderate	500 mg	q 12 h	10 days
Skin and Skin Structure	Mild/Moderate	500 mg	q 12 h	7 to 14 days
	Severe/Complicated	750 mg	q 12 h	7 to 14 days
Bone and Joint	Mild/Moderate	500 mg	q 12 h	≥ 4 to 6 weeks
	Severe/Complicated	750 mg	q 12 h	≥ 4 to 6 weeks
Intra-Abdominal	Complicated	500 mg	q 12 h	7 to 14 days
Infectious Diarrhea	Mild/Moderate/Severe	500 mg	q 12 h	5 to 7 days
Typhoid Fever	Mild/Moderate	500 mg	q 12 h	10 days
Urethral and Cervical Gonococcal Infections	Uncomplicated	250 mg	single dose	single dose
Ihnalational anthrax (post-exposure)		500 mg	q h 12	60 days

PEDIATRIC DOSAGE GUIDELINES

Infection	Route of Administration	Dose (mg/kg)	Frequency	Total Duration
Complicated Urinary Tract or Pyelonephritis (patients from 1 to 17 years of age)	Oral	10 mg/kg to 20 mg/kg (maximum 750 mg per dose; not to be exceeded even in patients weighing > 51 kg)	Every 12 hours	10-21 days
Inhalational Anthrax (Post-Exposure)	Oral	15 mg/kg (maximum 500 mg per dose)	Every 12 hours	60 days

PRESENTATION
Cipotent 250mg & 500mg tablet is available in blister packs.
Cipotent 125mg/5ml & 250mg/5ml suspension is available in bottle.

STORAGE CONDITIONS AND INSTRUCTIONS
- Store below 30°C in a dry place, protect from light.
- To be dispensed on the prescription of a registered medical practitioner only.
- Keep out of the reach of children.

ہدایات:
- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
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ART No: 107/4