BACTALL ®

DESCRIPTION
BACTALL is the trade name of Ciprofloxacin, a systemic fluoroquinolone antibacterial agent.
Each Coated **BACTALL 250**, **500**, and **750** Tablet contains Ciprofloxacin 250, 500, and 750 mg, respectively, as Ciprofloxacin Hydrochloride.
Excipients: Microcrystalline cellulose, sodium starch glycollate type A, colloidal anhydrous silica, hydroxypropyl cellulose, magnesium stearate, opadry OY-21033.

CHEMISTRY
Ciprofloxacin Hydrochloride is: 1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, monohydrochloride, monohydrate.

CLINICAL PHARMACOLOGY
BACTALL (Ciprofloxacin) is a broad-spectrum anti-infective bactericidal fluoroquinolone active against a wide range of aerobic gram-positive and gram-negative organisms. Ciprofloxacin acts intracellularly by inhibiting topoisomerase II (DNA gyrase) and/or topoisomerase IV. Topoisomerases are essential bacterial enzymes and critical catalysts in the duplication, transcription, and repair of bacterial DNA. Ciprofloxacin is active in vitro against most Enterobacteriaceae, including Citrobacter diversus, C. freundii, and C. koseri; Enterobacter aerogenes and E. cloacae; Escherichia coli; Klebsiella oxytoca, K. ozaenae, and K. pneumoniae; Morganella morganii; Proteus mirabilis and P. vulgaris; Providencia alcalifaciens, P. rettgeri, and P. stuartii; Salmonella enteritidis and S. typhi; Shigella boydii, S. dysenteriae, S. flexneri, and S. sonnei; Vibrio cholerae, V. parahaemolyticus, and V. vulnificus; and Yersinia enterocolitica. Ciprofloxacin has good in vitro activity against penicillin-resistant strains of Neisseria gonorrhoeae, beta-lactamase-producing strains of Haemophilus influenzae and Moraxella (Branhamella) catarrhalis, and some gram-negative bacilli that are resistant to other antimicrobial agents. Ciprofloxacin is the most active fluoroquinolone against Pseudomonas aeruginosa. Ciprofloxacin has also good in vitro activity against Staphylococcus saprophyticus, S. epidermidis, and S. aureus, including methicillin-resistant (MRSA) strains; and against Chlamydia trachomatis, Mycoplasma hominis, Mycoplasma pneumoniae, and Legionella pneumophila. In addition, Ciprofloxacin has been found to be active against Bacillus anthracis both in vitro and by use of serum levels as a surrogate marker.
Streptococci, including S. pneumoniae, S. pyogenes, and Enterococcus faecalis; and Mycobacterium tuberculosis are all moderately susceptible to Ciprofloxacin in vitro.
Ciprofloxacin is rapidly and well absorbed from the gastrointestinal tract; bioavailability is approximatly 70-80%. It is widely distributed to most body fluids and tissues including skin, fat, muscle, bone, and cartilage. It also penetrates the cerebrospinal fluid.

INDICATIONS
- The treatment of bone and joint infections, lower respiratory tract infections, bacterial exacerbations of bronchitis, skin and soft tissue infections, bacterial prostatitis, and complicated and uncomplicated urinary tract infections, including cystitis, caused by susceptible micro organisms.
- The treatment of infectious diarrhea caused by enterotoxigenic strains of Campylobacter jejuni, E. coli, S. boydii, S. dysenteriae, S. flexneri, or S. sonnei.
- The treatment of complicated intra-abdominal infections caused by Bacteroides fragilis, E. coli, K. pneumoniae, P. mirabilis, or P. aeruginosa, in combination with Metronidazole.
- The treatment of acute sinusitis caused by H. influenzae, M. catarrhalis, or S. pneumoniae.
- The treatment of typhoid fever caused by susceptible strains of Salmonella typhi.
- The treatment of endocervical and urethral gonorrheal infections caused by Neisseria gonorrhoeae.
- Treatment of inhalational anthrax: **BACTALL** is indicated to reduce the incidence or progression of the disease following exposure to aerosolized Bacillus anthracis
- **BACTALL** is used in the treatment of chancroid caused by Haemophilus ducreyi, and in the treatment of asymptomatic carriers of Neisseria meningitidis for the elimination of meningococci from the nasopharynx.
- **BACTALL** is also used in patients with cystic fibrosis for the treatment of pulmonary exacerbations caused by susceptible P. aeruginosa, alone or in combination with other antibacterial agents.

Note: Not all species or strains of a particular microorganism may be susceptible to **BACTALL.**

DOSAGE
Usual adult dose
- Bone and joint infections

Mild or moderate: 500 mg every 12 hours for at least 4-6 weeks and in severe or complicated: 750 mg every 12 hours for at least 4-6 weeks.
- Skin and soft tissue infections:

Mild or moderate: 500 mg every 12 hours for 7-14 days and in severe or complicated: 750 mg every 12 hours for 7-14 days.
- Mild or moderate chronic Prostatitis: 500 mg every 12 hours for 28 days.
- Urinary tract infections:

Acute uncomplicated: 100mg every 12 hours for 3 days and in mild or moderate: 250 mg every 12 hours for 7-14 days and in severe or complicated: 500 mg every 12 hours for 7-14 days
- Mild to severe infectious diarrhea: 500 mg every 12 hours for 5 to 7 days.
- Intra-abdominal infections:500 mg every 12 hours for 7-14 days, in combination with oral Metronidazole.
- Lower respiratory tract infections:

Mild to moderate: 500 mg every 12 hours for 7-14 days and in severe or complicated: 750 mg every 12 hours for 7-14 days.
- Sinusitis, mild or moderate or typhoid fever: 500 mg every 12 hours for 10 days.
- Endocervical and urethral gonorrhea: 250 mg as a single dose.
- Meningococcal carriers: 750 mg as a single dose.
- Treatment of inhalational anthrax: 500 mg every 12 hours for 60 days.

Usual pediatric dose
- Pulmonary exacerbations of cystic fibrosis:
  – Children 14 to 28 kg: 20 to 28 mg/kg every 12 hours, up to 2 grams per day.
  – Children 28 to 42 kg: 15 to 20 mg/kg every 12 hours, up to 2 grams per day.
- Treatment of inhalational anthrax: 15 mg/kg per dose, not to exceed 500 mg per dose, every 12 hours for 60 days.

Notes
- **BACTALL** should be taken with a full glass of water, with meals or on an empty stomach.
- Adults with creatinine clearance (CrCl) > 50 ml/min may receive usual adult dose. If CrCl is 30-50 ml/min, dosage is 250 to 500 mg every 12 hours. If CrCl is 5-29 ml/min, dosage is 250 to 500 mg every 18 hours. In hemodialysis or peritoneal dialysis patients, dosage is 250-500 mg every 24 hours after dialysis. Patients with severe infection and severe renal function impairment may receive a unit dose of 750 mg at the intervals noted above; however, these patients should be monitored carefully.
- Use of fluoroquinolones in general is not recommended in children up to 18 years of age since they cause arthropathy in immature animals. However, Ciprofloxacin has been given to pediatric patients when alternative therapy could not be used.
- Based on pharmacokinetic studies, dosing for patients with cystic fibrosis should be higher and at more frequent intervals than for patients without cystic fibrosis. Dosing for cystic fibrosis patients also should be decreased as body weight increases.

ADVERSE EFFECTS
Ciprofloxacin generally is well tolerated, and adverse effects of the drug are similar to those reported with other quinolone anti-infective agents.
- More frequent effects: Nausea .
- Less frequent effects: Diarrhea, vomiting, abdominal pain/discomfort, headache, restlessness, and rash.
- Crystalluria is very unlikely to occur with Ciprofloxacin, unless urine becomes alkalinized.
- Seizures have rarely been reported in patients with previous seizure history, alcoholics, or patients taking theophylline concurrently with Ciprofloxacin.
- Achilles tendinitis and tendon rupture have been reported in patients receiving fluoroquinolones. Ciprofloxacin should be discontinued at the first sign of tendon pain or inflammation, and patients should refrain from exercise and inform their physicians.

USE IN PREGNANCY
Ciprofloxacin crosses the placenta. Adequate and well controlled studies in humans have not been done. However, because most fluoroquinolones caused arthropathy in immature animals, Ciprofloxacin should not be used in pregnant women. FDA Pregnancy Category C.

USE IN LACTATION
Ciprofloxacin is distributed into human breast milk. Fluoroquinolones have been shown to cause permanent lesions of the cartilage of weight-bearing joints, as well as other signs of arthropathy in immature animals. Therefore, breast-feeding is not recommended if an alternative antibiotic cannot be prescribed and Ciprofloxacin must be administered.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS
Serum values of alanine aminotransferase, alkaline phosphatase, amylase, aspartate aminotransferase and lactate dehydrogenase may be increased with Ciprofloxacin therapy.

DRUG INTERACTIONS
- Concurrent use of Ciprofloxacin with a theophylline derivative may result in higher and prolonged serum theophylline concentrations and may increase the risk of theophylline-related adverse effects. Serum theophylline concentrations should be monitored and dosage adjustments may be required.
- Ciprofloxacin absorption may be reduced by antacids, ferrous sulfate, zinc, or sucralfate resulting in lower serum and urine concentrations. Ciprofloxacin should be taken at least 2 hours before or 6 hours after any of these medications.
- Didanosine also reduces Ciprofloxacin absorption and should not be administered concurrently.
- Ciprofloxacin has resulted in a 34 to 80% decrease in plasma concentration of phenytoin. Phenytoin should be monitored when Ciprofloxacin is initiated or discontinued.
- Ciprofloxacin reduces the hepatic metabolism and clearance of caffeine, thus increasing its half-life and the risk of caffeine-related central nervous system (CNS) stimulation.
- Ciprofloxacin has been reported to increase the anticoagulant effect of warfarin, thus increasing the chance of bleeding. Prothrombin time should be carefully monitored in patients on concurrent treatment.
- Some quinolones, including Ciprofloxacin, have been associated with transient elevations in serum creatinine and serum cyclosporine concentrations in patients receiving cyclosporine concomitantly.
- Ciprofloxacin should not be taken concurrently with dairy products or with fortified drinks alone (e.g. milk, yoghurt, calcium fortified orange juice) because absorption of ciprofloxacin may be reduced.

CONTRAINDICATIONS
- Ciprofloxacin is contraindicated in patients with a history of hypersensitivity to the drug or to other quinolones.
- Ciprofloxacin should not be used in pregnant or lactating women (see Use In Pregnancy/Lactation).

WARNINGS
Risk-benefit ratio should be considered when the following medical problems exist:
- CNS disorders, including cerebral arteriosclerosis or epilepsy: because like other fluoroquinolones, Ciprofloxacin may cause CNS stimulation that potentially leads to CNS adverse effects.
- Ciprofloxacin is primarily excreted by kidneys. Patients with impaired renal function require a reduced dose of Ciprofloxacin (see Dosage).

OVERDOSE
Limited Information is available on the acute toxicity of Ciprofloxacin in humans. Since there is no specific antidote, treatment should be symptomatic and supportive, possibly utilizing stomach emptying by induction of emesis or gastric lavage, maintenance of adequate hydration and careful observation of the patient. In patients with serious toxic reactions, hemodialysis or peritoneal dialysis may enhance Ciprofloxacin elimination.

PRECAUTIONS
- Like other fluoroquinolones, Ciprofloxacin can cause serious hypersensitivity reactions. Patients should discontinue the drug and contact their physician at the first sign of rash or hypersensitivity.
- Ciprofloxacin may cause dizziness or lightheadedness. Caution should be exercised while operating a motor vehicle or machinery.
- Patients receiving Ciprofloxacin should be advised to avoid excessive exposure to sunlight or artificial ultraviolet light and to discontinue therapy if phototoxicity occurs.

HOW SUPPLIED
- Boxes of 10 blistered tablets of **BACTALL 250**.
- Boxes of 10 blistered tablets of **BACTALL 500.**
- Boxes of 10 blistered tablets of **BACTALL 750.**
- Hospital packs of different presentations.

Store at a tmeperture between 15 and 30 °C.
Do not use after the expiry date shown on the package.

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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COUNCIL OF ARAB HEALTH MINISTERS
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request

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