

# Ocimax

## Ciprofloxacin

### Composition

**Ocimax 500 Tablet:** Each film coated tablet contains Ciprofloxacin Hydrochloride BP equivalent to Ciprofloxacin 500 mg.

**Ocimax Pellets for Suspension 60 ml:** After reconstitution each 5 ml suspension contains Ciprofloxacin USP 250 mg.

### Pharmacology

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.

### Indication

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 emphyema.

**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.

### Dose and Administration

a) Route of administration: Oral

**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 Prostatitis             | 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

### Contraindication

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

### Warning & Precaution

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.

### Side effects

a) **Common:** 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.

b) **Rare:** Joint pain, light sensitivity, transient increase in liver enzyme (especially in patients with history of liver damage), serum bilirubin, urea or serum creatinine. Arthralgia, myalgia and risk of retinal detachment.

### 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.

### Use in 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.

### Drug interaction

a) **With Medicine:** 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.

b) **With food & others:** Ciprofloxacin should not be taken concurrently with milk or other dairy products, since absorption of Ciprofloxacin may be significantly reduced. Dietary calcium is a part of a meal, however, does not significantly affect the absorption of Ciprofloxacin.

### Overdose

Overdose following Ciprofloxacin administration may lead to seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria, haematuria & reversible renal toxicity.

### Information for patients

Ocimax 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.

### Storage

Store below 30°C. Protect from light and moisture. Keep all medicines out of reach of children.

### Packing

**Ocimax 500 Tablet:** Each box contains 30 (3x10's) tablet in Alu-PVC blister pack.

**Ocimax Pellets for Suspension 60 ml:** Each box contains one bottle of diluent & one bottle of Ciprofloxacin pellets with a dropper. After reconstitution as per direction bottle contains 60 ml suspension.



Manufactured by

**ONE PHARMA LTD.**

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OMX Rev.04