

Ciprofloxacin Tablet / Pellets for Suspension

Presentation

Geflox 250: Each film coated tablet contains Ciprofloxacin 250 mg (as Ciprofloxacin Hydrochloride USP). Geflox 200: Each fill coated tablet contains Ciprofloxacin 200 mg (as Ciprofloxacin Hydrochloride USP). Geflox XR: Each XR-tablet contains Ciprofloxacin 500 mg (as Ciprofloxacin Hydrochloride USP). Geflox Pellets for Suspension 60 ml: After reconstitution each 5 ml suspension contains Ciprofloxacin 250 mg (as Ciprofloxacin Hydrochloride BP).

Pharmacodynamics Ciprofloxacin inhibits the bacterial DNA gyrase or the topoisomerase IV enzyme, thereby inhibiting DNA replication and transcription. Quinolones can enter cells easily via porins and therefore are often used to treat intracellular pathogens such as *Legionella pneumophila* and *Mycoplasma pneumoniae*. For many gram-negative bacteria DNA gyrase is the target, whereas topoisomerase IV is the target for many grampositive bacteria.

Pharmacokinetics

Pharmacokinetics Ciprofloxacin given orally is rapidly and well absorbed from the gastrointestinal tract & widely distributed throughout the body. The binding of Ciprofloxacin to serum proteins is 20 to 40%. Tissue concentration often exceed serum concentration in both men and women. The serum elimination half-life in subjects with normal renal function is approximately 4 hours. Approximately 40 to 50% of an oral dose of Ciprofloxacin is excreted in the urine within 24 hours as unchanged drug and biologically active metabolites. Indications

Intra-abdominal infections

Gonorrhea Inhalational anthrax

Infections of the biliary tract Gastrointestinal infections Severe systemic infections

- Respiratory tract infections
 Ear, nose, and throat infections
 Eye infections

- Urinary tract infections
 Skin and soft tissue infections
 Bone and joint infections

Dosage & Administration Adults

General dosage recommendations

| Infections | Type or severity | Unit dose | Frequency | Usual duration | |
|--|-----------------------|-----------|--------------|------------------------------|--|
| Urinary tract | Acute uncomplicated | 250 mg | 12 hourly | 3 days | |
| | Mild/Moderate | 250 mg | 12 hourly | 7 to 14 days | |
| | Severe/Complicated | 500 mg | 12 hourly | 7 to 14 days | |
| Chronic Bacterial Prostatitis | Mild/Moderate | 500 mg | 12 hourly | 28 days | |
| Lower respiratory tract | Mild/Moderate | 500 mg | 12 hourly | 7 to 14 days | |
| | Severe/Complicated | 750 mg | 12 hourly | 7 to 14 days | |
| Acute sinusitis | Mild/Moderate | 500 mg | 12 hourly | 10 days | |
| Skin & skin structure | Mild/Moderate | 500 mg | 12 hourly | 7 to 14 days | |
| | Severe/Complicated | 750 mg | 12 hourly | 7 to 14 days | |
| Bone & joint | Mild/Moderate | 500 mg | 12 hourly | ≥ 4 to 6 weeks | |
| | Severe/Complicated | 750 mg | 12 hourly | ≥ 4 to 6 weeks | |
| Intra-abdominal * | Complicated | 500 mg | 12 hourly | 7 to 14 days | |
| Infectious diarrhea | Mild/Moderate/ Severe | 500 mg | 12 hourly | 5 to 7 days | |
| Typhoid fever | Mild/Moderate | 500 mg | 12 hourly | 10 days | |
| Urethral and Cervical Gonococcal Infections | Uncomplicated | 250 mg | Single dose | , | |
| Inhalational anthrax (post-exposure) | | 500 mg | 12 hourly | 60 days | |
| Dosage of Geflox-XR | | | * Used in co | njunction with metronidazole | |
| Infections | Type or severity | Unit dose | Frequency | Usual duration | |
| Urinary tract infections (Acute cystitis) | Uncomplicated | 500 mg | Once daily | 3 days | |
| | Complicated | 1000 mg | Once daily | 7 to 14 days | |

Pediatric dosage guideline (1 year & above)

Acute uncomplicated

| Infections | Type or severity | Dose | Frequency | Usual duration |
|---|------------------|-------------------------------|-----------|----------------|
| Urinary tract or Pyelonephritis | Complicated | 10-20 mg/kg (max 750 mg/dose) | 12 hourly | 10-21 days |
| Typhoid fever | Mild/Moderate | 10-20 mg/kg | 12 hourly | 7-14 days |
| Shigellosis | | 10-20 mg/kg | 12 hourly | 5 days |
| Acute Invasive diarrhea | | 10-30 mg/kg | 12 hourly | 3 days |
| Inhalational anthrax (Post Exposure) | | 15 mg/kg (max 500 mg/dose) | 12 hourly | 60 days |

1000 mg

Once daily

7 to 14 days

In acute uncomplicated pyelonephritis where 1000 mg is the appropritate dose, the dosage of Ciprofloxacin-XR should be reduced to 500 mg-XR tablet daily in patients with creatinine clearance below 30 ml/min.

Missed Dose

Pyelonephritis

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule.

Contraindications

Ciprofloxacin is contraindicated in patients who have shown hypersensitivity to Ciprofloxacin.

Side Effects

Ciprofloxacin is generally well tolerated. The most frequently reported adverse reactions are nausea, diarrhea, vomiting, abdominal pain, discomfort, headache, restlessness and rash.

Precautions

Ciprofloxacin should be used with caution in epileptics and patients with a history of CNS disorders and only if the benefits of the treatment are considered to outweigh the risk of possible CNS side effects. Alteration of the dosage regimen is necessary for patients with impaired renal function.

Drug Interactions

When Ciprofloxacin tablet is given concomitantly with food, there is a delay in the absorption of the drug whereas there is no delay observed when Ciprofloxacin suspension is given with food. Concurrent administration of antacids containing magnesium hydroxide or aluminum hydroxide may reduce the bioavailability of Ciprofloxacin by as much as 90%. Ciprofloxacin may increase the effects of theophylline and caffeine.

Use in Pregnancy and Lactation

Not recommended.

Storage Condition

Store in a cool and dry place, protect from light and out of children's reach. Discard the reconstituted suspension of unused portion after 14 days. Direction for Reconstitution

Pour the diluent of small bottle into large bottle. No need to add extra water. Now shake the bottle well until the pellets are fully dispersed.

Commercial Pack

Geflox 250: Each box contains 3 blister packs of 10 tablets. Geflox 500: Each box contains 3 Alu-Alu blister packs of 10 tablets. Geflox XR: Each box contains 2 blister packs of 10 tablets. Geflox Pellets for Suspension 60 ml : Each pack contains 1 bottle Ciprofloxacin pellets accompanied by 1 bottle of diluent for 60 ml suspension.

