

# CP

## (Cefpodoxime Proxetil)

Tablet / Powder for Suspension/Paediatric Drops

### Description

**CP** (Cefpodoxime Proxetil) is a broad-spectrum semi-synthetic 3rd generation oral Cephalosporin antibiotic. Cefpodoxime Proxetil is a prodrug; its active metabolite is Cefpodoxime. It has good stability to beta lactamase and the susceptible organisms include gram-positive bacteria e.g., *S. aureus*, (including penicillinase producing strains), *S. saprophyticus*, *S. pneumoniae*, *S. pyogenes*, *S. agalactiae*, *P. magnus* and gram-negative bacteria e.g., *E. coli*, *K. pneumoniae*, *H. influenzae* (including  $\beta$ -lactamase producer & Ampicillin resistant strains), *M. catarrhalis*, *N. gonorrhoeae* (including penicillinase producing strains), *P. mirabilis*, *C. diversus*, *H. parainfluenzae*, *K. oxytoca*, *P. vulgaris*, *P. rettgeri*. Like other  $\beta$ -lactam antibiotics it is a bactericidal drug that acts by inhibition of bacterial cell wall synthesis.

### Composition

**CP 200 tablet:** Each film-coated tablet contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 200 mg.

**CP powder for suspension:** After reconstitution each 5 ml suspension contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 40 mg.

**CP Paediatric Drops :** After reconstitution each ml drop contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 20 mg.

### Indications

**CP** (Cefpodoxime Proxetil) is indicated in the following diseases:

- (1) **Lower respiratory tract infection:** Acute community-acquired pneumonia, Acute bacterial exacerbation of chronic bronchitis;
- (2) **Upper respiratory tract infection:** Acute otitis media, Acute maxillary sinusitis, Pharyngitis, Tonsillitis;
- (3) **Sexually transmitted diseases:** Acute uncomplicated urethral & cervical gonorrhea, Acute ano-rectal infection in woman caused by *N. gonorrhoeae*;
- (4) **Uncomplicated urinary tract infection:** Cystitis;
- (5) **Skin & soft tissue infections:** Furuncle, Cellulitis, Subcutaneous abscess, Infectious atheroma & Periproctal abscess.
- (6) **Childhood infections**

### Dosage and Administration

**CP** (Cefpodoxime Proxetil) tablet should be administered orally with food to enhance absorption. **CP** (Cefpodoxime Proxetil) suspension may be given without regard to food.

The recommended doses, durations of treatment, applicable patient populations are as below:

#### Adults and adolescents (age 12 years and older):

Type of Infection	Dose Frequency	Duration
Acute community-acquired pneumonia	200 mg 12 hourly	14 days
Acute bacterial exacerbations of chronic bronchitis	200 mg 12 hourly	10 days
Uncomplicated gonorrhea (men/women)	Single dose 200 mg	
Rectal gonococcal infection in women	Single dose 200 mg	
Skin & Skin structure infection	400 mg 12 hourly	7-14 days
Pharyngitis and/or tonsillitis	100 mg 12 hourly	5-10 days
Uncomplicated urinary tract infection	100 mg 12 hourly	7 days
Acute maxillary sinusitis	200 mg 12 hourly	10 days

#### Child:

15 days - 6 months : 4 mg / kg every 12 hours

6 months - 2 years : 40 mg every 12 hours

3 - 8 years : 80 mg every 12 hours

Over 9 years : 100 mg every 12 hours

**Patients with renal dysfunction:** For patients with severe renal impairment (creatinine clearance <30 ml/min) the dosing intervals should be increased to 24 hourly.

**Patients with liver cirrhosis:** Cefpodoxime Proxetil pharmacokinetics in cirrhotic patients are similar to those in healthy subjects. Dose adjustment is not necessary in this population.

**OR AS DIRECTED BY THE PHYSICIAN**

### Side effect

Cefpodoxime has very few side effects. Possible side effects including gastrointestinal disorders (such as diarrhoea, nausea, vomiting and abdominal pain), rash, urticaria and itching.

### Precaution

In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of Cefpodoxime should be reduced. Cefpodoxime, like other cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics. As with other broad spectrum antibiotics, prolonged use of Cefpodoxime Proxetil may result in over growth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential.

### Contraindication

Cefpodoxime is contraindicated in patients with a known allergy to Penicillins, Cefpodoxime or other Cephalosporins group of antibiotics.

### Use in pregnancy and lactation

Pregnancy category of Cefpodoxime is B. It was neither teratogenic nor embryocidal in animal trial. However, there are no adequate and well-controlled studies of Cefpodoxime use in pregnant women. The drug should be used during pregnancy only if clearly needed. Cefpodoxime is excreted in human milk. A decision should be made whether to discontinue breast-feeding or to discontinue the drug taking into account the importance of the drug to the mothers.

### Drug Interactions

**Antacids:** Concomitant administration of high doses of antacids (Sodium bicarbonate and Aluminum hydroxide) or  $H_2$  blockers reduces peak plasma level by 24% to 42% and the extent of absorption by 27% to 32%, respectively.

**Probenecid:** Renal excretion of Cefpodoxime was inhibited by probenecid and resulted in an approximately 31% increase in AUC.

**Nephrotoxic drugs:** Close monitoring of renal function is advised when Cefpodoxime is administered concomitantly with compounds of known nephrotoxic potential.

### Overdosage

The symptoms following an overdose of Cefpodoxime antibiotic may include nausea, vomiting, epigastric distress and diarrhea.

### Direction for Reconstitution of Suspension

First shake the bottle to loosen powder. Add 30 ml (by using the supplied measuring cup) boiled and cooled water to the bottle in two portions, shake well after each addition. Keep the bottle tightly closed.

The reconstituted suspension should be kept in a cool and dry place, preferably in refrigerator. Unused portion should be discarded after 14 days.

### Direction for Reconstitution of Paediatric Drops

Shake the bottle well before adding water to loosen the powder. Add 8 ml (2 spoonful of the supplied spoon) boiled and cooled water to the bottle in two portions. Shake well the bottle after each addition.

The reconstituted drops should be kept in a cool and dry place, preferably in refrigerator. Unused portion should be discarded after 14 days.

### Supply

**CP 200 tablet:** Each box contains 2x4 tablets in Alu-Alu blister strips.

**CP powder for suspension:** Each bottle contains Cefpodoxime powder for 50 ml suspension. A 2.5 ml dropper and a 10 ml measuring cup is given.

**CP Paediatric Drops :** Each bottle contains Cefpodoxime powder for 15 ml Paediatric Drops. A dropper and a spoon is given.

Keep all medicines out of reach of children.

Store in a cool and dry place protected from light.

★ Further information is available on request.



Manufactured by:

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