CEFOMATIC-DT

Each tablet contains Cefpodoxime 200 mg

Dosage Form and Strength

Dosage Form: Dispersible Tablet.

Dosage Strength: Cefpodoxime 200 mg per tablet.

CLINICAL PARTICULARS

Therapeutic indications:

- Cefpodoxime Proxetil is indicated for the treatment of patients with mild to moderate infections caused bysusceptible strains of the designated microorganisms in the conditions listed below.
- Recommended dosages, durations of therapy, and applicable patient populations vary among these infections.
- Acute otitis media caused by Streptococcus pneumoniae (excluding penicillin-resistant strains), Streptococcus pyogenes, Haemophilus influenzae (including beta-lactamase-producing strains), or Moraxella (Branhamella) catarrhalis (including beta-lactamase-producing strains).
- Pharyngitis and/or tonsillitis caused by Streptococcus pyogenes.
- Community-acquired pneumonia caused by S. pneumoniae or H. Influenzae (including beta-lactamase- producing strains).
- Acute bacterial exacerbation of chronic bronchitis caused by S. pneumoniae, H. influenzae (non-beta- lactamase-producing strains only), or M. catarrhalis. Data are insufficient at this time to establish efficacy in patients with acute bacterial exacerbations of chronic bronchitis caused by beta-lactamase-producing strains of H. influenzae.
- Acute, uncomplicated urethral and cervical gonorrhea caused by Neisseria gonorrhoeae (including penicillinase-producing strains).
- Acute, uncomplicated ano-rectal infections in women due to Neisseria gonorrhoeae (including penicillinase-producing strains).
- Uncomplicated skin and skin structure infections caused by Staphylococcus aureus (including penicillinase-producing strains) or Streptococcus pyogenes. Abscesses should be surgically drained as clinically indicated.
- Acute maxillary sinusitis caused by Haemophilus influenzae (including beta-lactamase-

producing strains), Streptococcus pneumoniae, and Moraxella catarrhalis.

- Uncomplicated urinary tract infections (cystitis) caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, or Staphylococcus saprophyticus.

Posology and method of administration:

The recommended dosages, durations of treatment, and applicable patient population are as described inthe following chart:

Adults and Adolescents (age 12 years and older)

Type of Infection	Total Daily Dose	Dose Frequency	Duration
Pharyngitis and/or tonsillitis	200 mg	100 mg Q 12 hours	5 to 10days
Acute community-acquired pneumonia	400 mg	200 mg Q 12 hours	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg Q 12 hours	10 days
Uncomplicated gonorrhea (men and women) and rectal gonococcal infections (women)	200 mg	single dose	
Skin and skin structure	800 mg	400 mg Q 12 hours	7 to 14days
Acute maxillary sinusitis	400 mg	200 mg Q 12 hours	10 days
Uncomplicated urinary tract infection	200 mg	100 mg Q 12 hours	7 days

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties:

Cefpodoxime is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefpodoxime has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative and Gram-positive bacteria.

Mechanism of Resistance

Resistance to Cefpodoxime is primarily through hydrolysis by beta-lactamase, alteration of penicillin-binding proteins (PBPs), and decreased permeability.

Cefpodoxime has been shown to be active against most isolates of the following bacteria, both in vitro and in clinical infections as described in the Indications and Usage:

Gram-positive bacteria

Staphylococcus aureus (methicillin-susceptible strains, including those producing penicillinases)

Staphylococcus saprophyticus

Streptococcus pneumoniae (excluding penicillin-resistant isolates)

Streptococcus pyogenes

Gram-negative

bacteria

Escherichia coli

Klebsiella

pneumoniae

Proteus mirabilis

Haemophilus influenzae (including beta-lactamase producing isolates)

Moraxella catarrhalis

Neisseria gonorrhoeae (including penicillinase-producing isolates)

Pharmacokinetic Properties:

Absorption and Excretion

Cefpodoxime proxetil is a prodrug that is absorbed from the gastrointestinal tract and de-esterified to its active metabolite, cefpodoxime. Following oral administration of 100 mg of cefpodoxime proxetil to fasting subjects, approximately 50% of the administered cefpodoxime dose was absorbed systemically. Over the recommended dosing range (100 to 400 mg), approximately 29 to 33% of the administered cefpodoxime dose was excreted unchanged in the urine in 12 hours. There is minimal metabolism of cefpodoxime in vivo.

Distribution

Protein binding of cefpodoxime ranges from 22 to 33% in serum and from 21 to 29% in plasma.