Combocef®

Cefpodoxime + Clavulanic Acid

Description

Combocef® is a combination of Cefpodoxime and Clavulanic Acid effective against multiple gram-positive and gram-negative bacteria and has well established safety and efficacy profile.

Cefpodoxime is an orally administered extended spectrum antibiotic of 3rd generation cephalosporin class.

The Clavulanic Acid in Combocef® protects Cefpodoxime from degradation by β-lactamase enzymes and effectively extends the spectrum to include many bacteria normally resistant to Cefpodoxime and other beta-lactam antibiotics. Thus, Combocef® possesses the distinctive properties of a broad spectrum antibiotic and a β-lactamase inhibitor.

Indications

Combocef® is indicated for the treatment of-

- URTIs
  - Pharyngitis
  - Tonsillitis
  - Acute maxillary sinusitis
- SSTIs
- UTIs
- Uncomplicated gonorrhea and rectal gonococcal infections
- Enteric fever
- LRTIs
  - Acute community acquired pneumonia
  - Acute bacterial exacerbations of chronic bronchitis

Dosage & administration

Dosage schedule for adults (Age 12 years and older)

Type of Infection	Total Daily Dosage	Dosage Frequency	Duration
Pharyngitis and/or tonsillitis	200 mg	100 mg 12 hourly	5 to 10 days
Acute community acquired pneumonia	400 mg	200 mg 12 hourly	14 days
Acute bacterial exacerbations of chronic bronchitis	400 mg	200 mg 12 hourly	10 days
Uncomplicated gonorrhea and rectal gonococcal infections	200 mg	Single dose	
Skin and skin structure infections	800 mg	400 mg 12 hourly	7 to 14 days
Acute maxillary sinusitis	400 mg	200 mg 12 hourly	10 days
Uncomplicated urinary tract infection	200 mg	100 mg 12 hourly	7 days
Enteric fever	400 mg	200 mg 12 hourly	7 to 14 days

Use in pregnancy & lactation

Pregnancy

Both Cefpodoxime and Clavulanic Acid are pregnancy category B.

Lactation

Cefpodoxime is excreted in human milk, so a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Special population

Patients with renal dysfunction

For patients with severe renal impairment (< 30 mL/min creatinine clearance), the dosing intervals should be increased to Q 24 hours. In patients maintained on hemodialysis, the dose frequency should be 3 times/week after hemodialysis.

Patients with cirrhosis

Cefpodoxime pharmacokinetics in cirrhotic patients (with or without ascites) are similar to those in healthy subjects. Dose adjustment is not necessary in this population.

Pediatric use

Safety and efficacy in infants less than 2 months of age have not been established.

Geriatric use

Dose adjustment in elderly patients with normal renal function is not necessary.

Side effects

This combination is well tolerated. Most common gastro-intestinal adverse effects seen is diarrhoea, nausea, vomiting and abdominal pain.

Precautions

Cross hypersensitivity in penicillin sensitive patients, leading to serious acute hypersensitivity reactions may need treatment with epinephrine along with other emergency measures such as intravenous fluids, oxygen, airway management and intravenous antihistamine, as clinically indicated. In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of cefpodoxime should be reduced because high and prolonged serum antibiotic concentrations can occur in such individuals following usual doses. Cefpodoxime, like other cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics.

Contraindications

It is contraindicated in patients with known allergy to Cefpodoxime and Clavulanic Acid or to the Cephalosporin group of antibiotics.

Drug interactions

Antacids: Concomitant administration of high doses of antacids (sodium bicarbonate and aluminum hydroxide) or H_2 blockers reduce peak plasma level by 24% to 42% and the extent of absorption by 27% to 32% respectively.

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

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

Pharmaceutical precautions

Store in a cool (below 25°C) & dry place. Protect from light.

Presentation

Combocef ® 100 Tablet : Each coated tablet contains Cefpodoxime 100 mg as Proxetil USP and Clavulanic Acid 62.5 mg as diluted Potassium Clavulanate BP.

Combocef ® 200 Tablet : Each coated tablet contains Cefpodoxime 200 mg as Proxetil USP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.

Package quantities

Combocef ® 100 Tablet : Carton of 12 tablets in blister pack.
Combocef ® 200 Tablet : Carton of 12 tablets in blister pack.

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