Ceroclav

Cefuroxime + Clavulanic Acid

Description

Cefuroxime is a broad spectrum second generation Cephalosporin active against a wide range of Gram-positive and Gram-negative susceptible organisms including many beta-lactamase producing strains. The bactericidal action of Cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins. Cefuroxime has good stability to bacterial beta-lactamases.

Clavulanic Acid has a similar structure to the beta-lactam antibiotics but binds irreversibly to the beta-lactamase enzymes. The presence of Clavulanic Acid protects Cefuroxime from degradation by beta-lactamase enzymes and effectively extends the antibacterial spectrum of Cefuroxime to include many bacteria normally resistant to Cefuroxime and other Cephalosporins.

Composition

Ceroclav 250 Tablet: Each tablet contains Cefuroxime 250 mg as Cefuroxime Axetil USP and Clavulanic Acid 62.5 mg as diluted Potassium Clavulanate BP.

Ceroclav 500 Tablet: Each tablet contains Cefuroxime 500 mg as Cefuroxime Axetil USP and Clavulanic Acid 125 mg as diluted Potassium Clavulanate BP.

Ceroclav 70 ml Powder for Suspension: Each 5 ml reconstituted suspension contains Cefuroxime 125 mg as Cefuroxime Axetil USP and Clavulanic Acid 31.25 mg as diluted Potassium Clavulanate BP.

Indication

Pharyngitis/Tonsillitis, Acute Bacterial Otitis Media, Uncomplicated Skin and Skin-Structure Infections, Uncomplicated Urinary Tract Infections, Uncomplicated Gonorrhea, Lyme disease, Septicemia, Meningitis, Switch therapy (injectable to oral).

Dosage & Administration

Ceroclav Tablets: Adults (13 years and older)

Infection	Dosage	Duration (days)
Pharyngitis/Tonsillitis	250 mg b.i.d.	5-10
Acute Bacterial Maxillary Sinusitis	250 mg b.i.d.	10
Acute Bacterial Exacerbations of Chronic Bronchitis	250 - 500 mg b.i.d.	10
Secondary Bacterial Infections of Acute Bronchitis	250 - 500 mg b.i.d.	5-10
Uncomplicated Skin and Skin-Structure Infections	250 - 500 mg b.i.d.	10
Community Acquired Pneumonia	250-500 mg b.i.d.	5-10
Typhoid fever	500 mg b.i.d.	10-14
Uncomplicated Urinary Tract Infections	250 mg b.i.d.	7-10
Uncomplicated Gonorrhea	1,000 mg single dose	-
Lyme Disease	500 mg b.i.d.	20

Pediatric Patients (03 months to 12 years, who can swallow tablet whole)

Infection	Dosage	Duration (days)
Acute Otitis Media	250 mg b.i.d.	10
Acute Bacterial Maxillary Sinusitis	250 mg b.i.d.	10

Cefuroxime-Clavulanic Acid tablet may be taken without regard of food.

Ceroclav Suspension: Can be administered to pediatric patients ranging in age from 3 months to 12 years. Must be administered with food. Shake well each time before using.

Infection	Dosage	Daily Maximum dose	Duration (days)
Pharyngitis/Tonsillitis	20 mg/kg/day b.i.d.	500 mg	10
Acute otitis media	30 mg/kg/day b.i.d.	1000 mg	10
Acute Bacterial Maxillary Sinusitis	30 mg/kg/day b.i.d.	1000 mg	10
Impetigo	30 mg/kg/day b.i.d.	1000 mg	10

Side effect

Generally Cefuroxime-Clavulanic Acid is well tolerated. Major adverse reactions which may occur are diarrhea, nausea, vomiting and eosinophilia. Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion, headache, vaginitis, rash, itch, dysuria, sleepiness, thirst, anorexia etc.

Contraindication

It is contraindicated in patients with known allergy to Cephalosporins & in patients with pseudomembranous Colitis.

Drug interaction

Concomitant administration of Probenecid with Cefuroxime-Clavulanic Acid increases the area under the serum concentration versus time curve by 50%. Drug that reduces gastric acidity may result in a lower bioavailability of Cefuroxime and tend to cancel the effect of postprandial absorption

Precaution

As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime and Clavulanic Acid combination may result in overgrowth of nonsusceptible microorganisms.

Use in pregnancy & lactation

All antibiotics should be avoided in the first trimester if possible. However, Cefuroxime-Clavulanic Acid can be safely used in later pregnancy to treat Urinary Tract and other infections. Cefuroxime-Clavulanic Acid is excreted into the breast milk in small quantities and consequently caution should be exercised when it is administered to a nursing mother.

Storage

Store below 25°C, protected from light & moisture. Keep out of reach of children.

How supplied

Ceroclav 250 Tablet: Each box contains 2 x 7 tablets in Alu-Alu blister in Alu-Alu sachet.

Ceroclav 500 Tablet: Each box contains 1 x 7 tablets in Alu-Alu blister in Alu-Alu sachet.

Ceroclav 70 ml Powder for Suspension: Each box contains a bottle having powder to reconstitute 70 ml suspension.

Manufactured by:
Popular Pharmaceuticals Ltd. for
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