Cerox CV®

Cefuroxime Axetil + Clavulanic acid

Descriptions

Cerox CV® is a combination of Cefuroxime Axetil and Clavulanic Acid. Cefuroxime is a bactericidal second generation cephalosporin antibiotics, which is effective against a wide range of gram-positive and gram-negative organisms including many beta-lactamase producing strains.

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

Indications

- Pharyngitis and/or tonsillitis
- Acute bacterial otitis media
- Acute bacterial maxillary sinusitis
- Lower respiratory tract infections including pneumonia
- Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis
- Skin and skin-structure infections
- Urinary tract infections
- Bone and Joint infections
- Gonorrhea: Uncomplicated and disseminated gonococcal infections
- Early Lyme disease (erythema migrans)
- Septicemia
- Meningitis
- Switch therapy (injectable to oral) after surgery when patient's condition is improved.

Dosage & Administration

Adolescents and adults (13 years and older)

Type of Infection	Total Daily Dosage	Dosage Frequency	Duration
Pharyngitis and/or tonsillitis	500 mg	250 mg 12 hourly	10 days
Acute bacterial maxillary sinusitis	500 mg	250 mg 12 hourly	10 days
Acute bacterial exacerbations of chronic bronchitis	500 mg or 1000 mg	250 mg or 500 mg 12 hourly	10 days
Secondary bacterial infections of acute bronchitis	500 mg or 1000 mg	250 mg or 500 mg 12 hourly	5-10 days
Uncomplicated skin and skin-structure infections	500 mg or 1000 mg	250 mg or 500 mg 12 hourly	10 days
Uncomplicated urinary tract infections	500 mg	250 mg 12 hourly	7-10 days
Uncomplicated gonorrhea	-	1000 mg once	Single dose
Early Lyme disease	1000 mg	500 mg 12 hourly	20 days
Acute otitis media	500 mg	250 mg 12 hourly	10 days

Pediatric patients (3 months to 12 years)

Oral Suspension must be administered with food. Shake the bottle well before each use.

Infection	Dosage	Daily Maximum Dose	Duration
Pharyngitis/tonsillitis	20 mg/kg/day divided b.i.d.	500 mg	10 days
Acute otitis media	30 mg/kg/day divided b.i.d.	1000 mg	10 days
Acute bacterial maxillary sinusitis	30 mg/kg/day divided b.i.d.	1000 mg	10 days
Impetigo	30 mg/kg/day divided b.i.d.	1000 mg	10 days

Direction for preparation/reconstitution of suspension

Shake the bottle well before mixing the water. To prepare 70 ml suspension, add 55 ml (11 teaspoonful) boiled and cooled water in two portions and shake well after each addition till powder is completely mixed with water.

The reconstituted suspension must be kept in $2^{o}C$ - $8^{o}C$ temperature in a refrigerator and consumed within 7 days after reconstitution.

Pregnancy & Lactation

Pregnancy

Both Cefuroxime and Clavulanic Acid are pregnancy category B.

Lactation

Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime.

Side effects

Generally Cefuroxime and Clavulanic Acid are well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime and Clavulanic Acid combination may result in overgrowth of non-susceptible microorganisms. Rare side effects are renal dysfunction, anaphylaxis, angioedema, pruritus, rash and serum sickness like urticaria may appear.

Contraindications

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

Warnings and Precautions

Prescribing Cefuroxime and Clavulanic Acid combination in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Cefuroxime should be given with caution to patients receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function. Cefuroxime, as with other broad-spectrum antibiotics, should be prescribed with caution in individuals with a history of colitis.

Drug interactions

Probenecid: Concomitant administration of probenecid with Cefuroxime increases the area under the serum concentration versus time curve by 50%. The peak serum Cefuroxime concentration after a 1.5 g single dose is greater when taken with 1 g of probenecid than without probenecid.

Antacids: Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime and Clavulanic Acid compared with that of fasting state and tend to cancel the effect of postprandial absorption.

Oral contraceptives: In common with other antibiotics, Cefuroxime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone.

Overdose

Signs and symptoms: Overdosage of Cerox CV® can cause cerebral irritation leading to convulsions.

Management: Serum level of Cerox CV® can be reduced by haemodialysis and peritoneal dialysis.

Pharmaceutical precautions

Store in a cool (below 25^{o}C) and dry place protected from light.

Presentation

Cerox CV® 125 Tablet: Each coated tablet contains Cefuroxime 125 mg as Axetil USP and Clavulanic Acid 31.25 mg as diluted Potassium Clavulanate BP.

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

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

Cerox CV® Powder for Suspension: Each 5 ml contains Cefuroxime 125 mg as Axetil USP and Clavulanic Acid 31.25 mg as diluted Potassium Clavulanate BP.

Package quantities

Cerox CV® 125 Tablet: Carton of 12 tablets in blister pack in sachet.

Cerox CV® 250 Tablet: Carton of 12 tablets in blister pack in sachet.

Cerox CV® 500 Tablet: Carton of 8 tablets in blister pack in sachet.

Cerox CV® Powder for Suspension: Bottle of 70 ml with food grade dropper.

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