Axim CV

Cefuroxime & Clavulanic Acid

Composition:
Axim CV 250 Tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 250 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 62.50 mg.
Axim CV 500 Tablet: Each film coated tablet contains Cefuroxime Axetil USP equivalent to Cefuroxime 500 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.
Axim CV Powder for Suspension: After reconstitution each 5 ml suspension contains Cefuroxime Axetil USP equivalent to Cefuroxime 125 mg and Diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 31.25 mg.

Pharmacology:
Cefuroxime has bactericidal activity against a wide range of bacteria, including 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 is a naturally derived beta lactamase inhibitor produced by *Streptomyces clavuligerus*. It has similar structure to beta lactam antibiotics but binds irreversibly to beta-lactamase enzymes and inactivates them. Clavulanic acid gives protection of Cefuroxime from degradation by beta lactamase enzymes and provides a solution for the treatment of bacterial infections caused by beta lactam resistant bacteria.

Indications:
Axim CV is indicated for the treatment of the following infections caused by susceptible microorganisms:
- Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes*
- Acute Bacterial Otitis Media caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (including beta-lactamase-producing strains), *Moraxella catarrhalis* (including beta-lactamase-producing strains), or *Streptococcus pyogenes*
- Acute Bacterial Maxillary Sinusitis caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (non-beta-lactamase-producing strains only)
- Acute Bacterial Exacerbations of Chronic Bronchitis and Secondary Bacterial Infections of Acute Bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (beta-lactamase negative strains), or *Haemophilus parainfluenzae* (beta-lactamase negative strains)
- Uncomplicated Skin and Skin-Structure Infections caused by *Staphylococcus aureus* (including beta-lactamase-producing strains) or *Streptococcus pyogenes*
- Uncomplicated Urinary Tract Infections caused by *Escherichia coli* or *Klebsiella pneumoniae*.
- Uncomplicated Gonorrhea (urethral and endocervical) caused by penicillinase-producing and non-penicillinase-producing strains of *Neisseria gonorrhoeae* and uncomplicated gonorrhea, (rectal) in females, caused by non-penicillinase-producing strains of *Neisseria gonorrhoeae*.
- Lyme disease (erythema migrans) caused by *Borrelia burgdorferi*.
- Septicemia caused by *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Escherichia coli*, *Haemophilus influenzae* (including ampicillin-resistant strains) & Klebsiella spp.
- Meningitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (including ampicillin-resistant strains), *Neisseria meningitidis* & *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains)
- Switch therapy (Injectable to oral)

Dosage and Administration:

Patients	Indications	Dosage	Duration (Days)
Adolescents and Adults (13 years and older)	Pharyngitis/tonsillitis	250 mg twice daily	5-10
	Acute bacterial maxillary sinusitis	250 mg twice daily	10
	Acute bacterial exacerbations of chronic bronchitis	250-500 mg twice daily	10
	Secondary bacterial infections of acute bronchitis	250-500 mg twice daily	5-10
	Uncomplicated skin and skin-structure infections	250-500 mg twice daily	10
	Uncomplicated urinary tract infections	250 mg twice daily	7-10
	Uncomplicated gonorrhea	1000 mg	Single dose
	Community acquired pneumonia	250-500 mg twice daily	5-10
	MDR Typhoid fever	500 mg twice daily	10-14
	Lyme disease	500 mg twice daily	20
Pediatric Patients (3 months to 12 years)	Pharyngitis/tonsillitis	20 mg/kg/day in 2 divided dose	5-10
	Acute otitis media	30 mg/kg/day in 2 divided dose	10
	Acute bacterial maxillary sinusitis	30 mg/kg/day in 2 divided dose	10
	Uncomplicated skin & skin-structure infections	30 mg/kg/day in 2 divided dose	10
	Community acquired pneumonia	30 mg/kg/day in 2 divided dose	5-10
	MDR Typhoid fever	30 mg/kg/day in 2 divided dose	10-14
	Uncomplicated urinary tract infection	20 mg/kg/day in 2 divided dose	7-10

Direction for reconstitution of suspension:
Shake the bottle well to loosen the powder. Add 60 ml (12 tea-spoonfuls) of boiled and cooled water to the dry powder of the bottle. Then shake the bottle well until all the powder is in suspension. The reconstituted suspension must be kept in 2^0 - 8^0 C temperature in a refrigerator and should be used within 7 days after reconstitution.

Contraindications:
Cefuroxime-Clavulanic Acid is contraindicated in patients with known allergy to cephalosporin & in patients with Pseudomembranous Colitis.

Precautions:
Cefuroxime-Clavulanic Acid should be given with care to patients receiving concurrent treatment with potent diuretics & who have history of Pseudomembranous Colitis.

Side Effects:
Generally Cefuroxime-Clavulanic Acid is 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 nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

Use in Special Group:
Use in pregnancy: While 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 and other infections.
Use in lactation: Cefuroxime-Clavulanic Acid is excreted into the breast milk in small quantities. However, the possibility of sensitizing the infant should be kept in mind.

Drug Interactions:
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.

Storage:
- Store below 25^0 C, keep in dry place & protect from light
- Keep out of the reach of children
- The reconstituted suspension must be kept in 2^0 - 8^0 C temperature in a refrigerator and should be used within 7 days after reconstitution

Packing:
Axim CV 250 Tablet: Each box contains 14 tablets in Alu-Alu blister within Alu-Alu pillow pack.
Axim CV 500 Tablet: Each box contains 14 tablets in Alu-Alu blister within Alu-Alu pillow pack.
Axim CV Powder for Suspension: Bottle containing dry powder for the reconstitution of 70 ml suspension.

Manufactured by:
ARISTOPHARMA LTD.
GAZIPUR, BANGLADESH

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