Xinarox CV

Cefuroxime & Clavulanic Acid

Cefuroxime is a bactericidal second generation cephalosporin antibiotic which is active against a wide range of Gram-positive and Gram-negative susceptible organisms including many beta-lactamase producing strains. Cefuroxime inhibits bacterial cell wall synthesis by interfering with the transpeptidation process.
Clavulanic Acid is a naturally derived beta lactamase inhibitor produced by *Streptomyces clavuligerus*. It has similar structure to beta lactam antibiotics which 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.

COMPOSITION

***Xinarox 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.
***Xinarox 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.

INDICATION

It is indicated for the treatment of infections caused by sensitive bacteria.
1. Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes*.
2. Acute Bacterial Otitis Media caused by *Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis* (beta-lactamase producing strains) or *Streptococcus pyogenes*.
3. Acute bacterial maxillary sinusitis caused by *Streptococcus pneumoniae* or *Haemophilus influenzae* (non beta-lactamase producing strains)
4. Lower respiratory tract infections including pneumoniae, caused by *Streptococcus pneumoniae, Haemophilus influenzae* (including beta lactamase-producing strains), *Klebsiella spp.*, *Staphylococcus aureus* (penicillinase- and non-penicillinase-producing strains), *Streptococcus pyogenes, E. coli.*
5. Acute bacterial exacerbation 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).
6. Uncomplicated skin and skin-structure infections caused by *Staphylococcus aureus* (including beta-lactamase producing strains) or *Streptococcus pyogenes.*
7. Uncomplicated urinary tract infections caused by *E.coli* or *Klebsiella pneumoniae.*
8. Bone and Joint Infections caused by *Staphylococcus aureus* (penicillinase- and non-penicillinase-producing strains).
9. Uncomplicated Gonorrhoea caused by penicillinase-producing and non-penicillinase producing strains of *Neisseria gonorrhoeae.*
10. Early Lyme Disease (erythema migrans) caused by *Borrelia burgdorferi.*
11. Septicemia caused by *Staphylococcus aureus*, *Streptococcus pneumoniae*, *E.coli*, *Haemophilus influenzae* (including ampicillin-resistant strains) & *Klebsiella spp.*
12. Meningitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (including ampicillin-resistant strains), *Neisseria meningitidis* & *Staphylococcus aureus* (penicillinase and non-penicillinase producing strains)
13. Switch therapy (Injectable to oral)

DOSAGE AND ADMINISTRATION

Adolescents and 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 exacerbation 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
Uncomplicated urinary tract infections	250 mg b.i.d.	7-10
Uncomplicated Gonorrhoea	1000 mg	Single dose
Community acquired pneumonia	250-500 mg b.i.d.	5-10
MDR Typhoid Fever	500 mg b.i.d.	10-14
Early Lyme disease	500 mg b.i.d.	20

Paediatric Patients (3 months to 12 years)

Infection	Dosage	Duration (Days)
Pharyngitis/ Tonsillitis	20 mg/kg/day b.i.d	5-10
Acute otitis media	30 mg/kg/day b.i.d.	10
Acute bacterial maxillary sinusitis	30 mg/kg/day b.i.d.	10
Impetigo	30 mg/kg/day b.i.d.	10

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

SIDE EFFECT

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.

CONTRAINDICATION

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

PRECAUTION

Cefuroxime should be given with care to patients receiving concurrent treatment with potent diuretics & who has history of 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.

USE IN PREGNANCY AND LACTATION

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.

STORAGE CONDITION

Store in a cool and dry place (below 30^{o} C), away from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

***Xinarox CV* 250 Tablet:** Each box contains 12 tablets in Alu-Alu blister within Alu-Alu pillow pack.
***Xinarox CV* 500 Tablet:** Each box contains 8 tablets in Alu-Alu blister within Alu-Alu pillow pack.

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Comilla, Bangladesh.