Xinarox

Cefuroxime

COMPOSITION

***Xinarox* 250 Tablet:** Each film coated tablet contains Cefuroxime Axetil BP equivalent to Cefuroxime 250 mg.
***Xinarox* 500 Tablet:** Each film coated tablet contains Cefuroxime Axetil BP equivalent to Cefuroxime 500 mg.
***Xinarox* 750 mg IM/IV Injection:** Each vial contains sterile Cefuroxime Sodium USP equivalent to Cefuroxime 750 mg.
***Xinarox* 1.5 g IV Injection:** Each vial contains sterile Cefuroxime Sodium USP equivalent to Cefuroxime 1.5 g.

PHARMACOLOGY

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.

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. Skin and skin-structure infections caused by *Staphylococcus aureus* (including beta-lactamase producing strains) or *Streptococcus pyogenes.*
7. 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. Gonorrhoea caused by penicillinase-producing and non-penicillinase producing strains of *Neisseria gonorrhoeae.*
10. Early Lyme Disease (erythema migrans) caused by *Borrelia burgdorferi.*

DOSAGE AND ADMINISTRATION

Oral 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

Parenteral:
Adult: 750 mg three times daily by IM or IV injection. In severe infections, dose can be increased upto 1.5 gm three times daily by IV injection. The frequency may be increased to four times daily, if necessary, giving total daily doses of 3 to 6 gms.

Children (above 3 months of age): 30 - 100 mg/kg/day given in 3 or 4 equally divided doses. A dose of 60 mg/kg/day is appropriate for most of the infections.

Neonate: 30 - 100 mg/kg/day given in 2 or 3 equally divided doses.

Surgical prophylaxis: 1.5 gm by IV injection at induction of anaesthesia; up to 3 further doses of 750 mg may be given by IV/IM injection every 8 hours for high risk procedures.

Sequential therapy in adults:
Pneumonia: 1.5 gm IV injection twice daily for 2-3 days, followed by 500 mg twice daily (oral) for 7-10 days.
Acute exacerbations of chronic bronchitis: 750 mg twice daily (IM or IV injection) for 2-3 days, followed by 500 mg twice daily (oral) for 5-10 days. (Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.)

Other recommendations
In Gonorrhoea:
Adult: 1.5 gm as a single dose (as 2 x 750 mg injections intramuscularly with different sites, e.g. each buttock).

In Meningitis:
Adult: 3 gm IV injection three times daily.
Children (above 3 months of age): 200-240 mg/kg/day by IV injection in 3 or 4 divided doses reduced to 100 mg/kg/day after 3 days or on clinical improvement.
Neonate: 100 mg/kg/day by IV injection at initial dose, reduced to 50 mg/kg/day, when clinically indicated.

In bone and joint infections:
Adult: 1.5 gm IV injection four times daily.
Children (above 3 months of age):
150 mg/kg/day (not to exceed the maximum adult dose) in equally divided doses every 8 hours.

In impaired renal function: A reduced dose must be employed when renal function is impaired. Dosage in adults should be determined by the degree of renal impairment and the susceptibility of the causative organism according to the table below-

Creatinine Clearance (ml/min)	Dose	Frequency
>20	750 mg-1.5 gm	q8h
10-20	750 mg	q12h
<10	750 mg	q24h*

* Since Cefuroxime is dialyzable, patients on hemodialysis should be given a further dose at the end of the dialysis.
In paediatric patients with renal insufficiency, the frequency of dosing should be modified consistent with the recommendations for adults.

Preparation of Solutions for Intramuscular/Intravenous Injections:
For 750 mg intramuscular injection: Add 3 ml Water for Injection USP to vial and then shake gently for dispersion.
For 750 mg intravenous injection: Add 8 ml Water for Injection USP to vial and then shake gently for dispersion. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.
For 1.5 g intravenous injection: Add 16 ml Water for Injection USP to vial and then shake gently for dispersion. The solution should be slowly injected directly into a vein over a 3 to 5 minutes period.

(The use of freshly reconstituted solution is recommended. However, it maintains potency for at least 24 hours at room temperature or 48 hours at 5°C).

CONTRAINDICATION

Cefuroxime is contraindicated in patients with known allergy to Cephalosporins.

WARNING AND PRECAUTION

Cefuroxime should be given with care to patients receiving concurrent treatment with potent diuretics and who has history of colitis. Cephalosporin antibiotics may in general be given safely to patients who are hypersensitive to penicillin although cross reactions have reported. Cefuroxime has shown, that is not likely to be a problem at the recommended to dose levels.

SIDE EFFECT

Adverse effects to Cefuroxime have occurred infrequently and have been generally mild and transient in nature. Effects reported include rashes and gastrointestinal disturbances. As with other antibiotics, prolonged use may result in the overgrowth of non susceptible organisms e.g. *Candida.*

USE IN PREGNANCY AND LACTATION

US FDA pregnancy category of Cefuroxime is B. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Cefuroxime have been shown to be excreted in human milk. So, caution should be exercised when Cefuroxime is administered to a nursing woman.

USE IN CHILDREN AND ADOLESCENTS

The safety and effectiveness of Cefuroxime have been established for paediatric patients aged 3 months to 12 years.

DRUG INTERACTION

No potentially hazardous interactions have been reported.

OVERDOSAGE

Overdosage of Cephalosporins (Cefuroxime) can cause cerebral irritation leading to convulsions or encephalopathy. Serum levels of Cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

STORAGE CONDITION

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

***Xinarox* 250 Tablet:** Each box contains 12 tablets in Alu-Alu blister pack.
***Xinarox* 500 Tablet:** Each box contains 6 tablets in Alu-Alu blister pack.
***Xinarox* 750 mg IV/IM Injection:** Each combipack contains one vial containing sterile Cefuroxime Sodium USP equivalent to Cefuroxime 750 mg, one ampoule of 10 ml of Water for Injection USP, one disposable syringe (10 ml) and a butterfly needle.
***Xinarox* 1.5 g IV Injection:** Each combipack contains one vial containing sterile Cefuroxime Sodium USP equivalent to Cefuroxime 1.5 gm, two ampoules of 10 ml of Water for Injection USP, one disposable syringe (20 ml) and a butterfly needle.

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NIPRO JMI Pharma

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