# Cefuroxime

## Cmaxid

Powder for Injection
Antibacterial

## Formulation

Cmaxid 750 : Each vial contains Sterile Cefuroxime Sodium U.S.P. equivalent to Cefuroxime 750 mg
Cmaxid 1.5 : Each vial contains Sterile Cefuroxime Sodium U.S.P. equivalent to Cefuroxime 1.5 g

## Description

White to faintly yellow powder
After reconstituted with Sterile water for Injection: Clear to pale yellow solution

## Actions and Pharmacology

All cephalosporins inhibit cell wall production and are selective inhibitors of peptidoglycan synthesis. The drug action consist of binding of the drug to bacterial cell receptors, the transpeptidation reaction is inhibited and peptidoglycan synthesis is blocked resulting bacterial lysis.

Cefuroxime Sodium is a second-generation cephalosporin and is commonly used to treat community-acquired pneumonias because of its activity against *S.pneumoniae, S.aureus* and *H.influenzae* (including ampicillin – resistant strains and *N. meningitidis.*

## Pharmacokinetics

**Absorption**

The sodium salt is given by intramuscular or intravenous injection. Peak plasma concentrations of about 27 micrograms/ml have been achieved 45 minutes after an intramuscular dose of 750 mg with measureable amount present 8 hours after a dose.

**Protein Binding**

Up to 50% of cefuroxime in the circulation is bound to plasma proteins. The plasma half-life is about 70 minutes and is prolonged in patients with renal impairment and in neonates.

**Distribution**

Cefuroxime is widely distributed in the body including pleural fluid, sputum, bone, synovial fluid and aqueous humour, but only achieves therapeutic concentration in the CSF when the meninges are inflamed. It crosses the placenta and has been detected in breast milk.

**Elimination**

Cefuroxime is excreted unchanged, by glomerular filtration and renal tubular secretion and high concentration occur in the urine.

## Indications

Used as an alternative drug for infections due to susceptible organisms such as in otitis media, orbital cellulitis, urinary tract, skin and soft tissue, bone and joint infections and post-splenectomy sepsis of unclear etiology.

## Precautions

Parenteral dosage of Cefuroxime should be modified in renal impairment and patients undergoing haemodialysis.

## Contraindications

This medication should not be used by patients with known allergy to cephalosporins, penicillins, penicillin derivatives or penicillamine.

## Use in Pregnancy and Lactation

Cefuroxime crosses placenta and is excreted in breast milk. Caution should be exercised when Cefuroxime is administered.

## Adverse Effects

Hypersensitivity reactions including skin rashes, urticaria, eosinophilia, fever, reactions resembling serum sickness, and anaphylaxis.
There have been rare reports of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis.
Gastrointestinal adverse effects such as nausea, vomiting and diarrhea have been reported rarely.
Prolonged use may results in overgrowth of non-susceptible organisms.

## Drug Interactions

Cefuroxime should not administer with aminoglycosides. If they were administered concurrently, they should be administered in separate sites.

## Overdose

Overdosage of cephalosporins can cause cerebral irritation leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

## Dosage and Administration

Cefuroxime sodium may be given by deep intramuscular injection, or by slow intravenous injection over 3 to 5 minutes, or by intermittent or continuous intravenous infusion.

**General Recommendations**

**Adult and Adolescent**

For most infections 750 mg three times a day. For more severe infections, dose may be increased to 1.5 g three times a day.

If necessary, the frequency of administration of Cefuroxime can be increase to four times a day up to total daily doses of 3 g to 6 g.

**Children from 1 month of age:**

20 mg/kg (to maximum dose of 750 mg) every 8 hours; this dose may be increased to 50 to 60 mg/kg (to a maximum dose of 1.5 g) every 6 or 8 hours in severe infection and cystic fibrosis.

For surgical prophylaxis, may be given a dose of 50 mg/kg (to a maximum dose of 1.5 g) intravenously before the procedure; this may be supplemented by up to 3 further doses of 30 mg/kg (to a maximum dose of 750 mg) intramuscularly or intravenously at 8 hour intervals for high-risks procedures.

**Neonates under 7 days of age:** 25 mg/kg every 12 hours

**Neonates under 7 to 21 days of age:** 25 mg/kg every 8 hours

**Neonates under 21 to 28 days of age:** 25 mg/kg every 6 hours

These doses may be doubled in neonates with severe infections, but should be given intravenously.

**Other Recommendations**

**Meningitis:** Cmaxid 1.5 is suitable for sole therapy of bacterial meningitis due to sensitive strains. Cmaxid 1.5 is given intravenously in doses of 3 g every 8 hours.

**Gonorrhoea:** 1.5 g should be given as a single dose. This may be given as 2 x 750 mg injections into different sites eg each buttock.

**Surgical infection prophylaxis:** The usual dose is 1.5 g (I.V.) with induction of anaethesia for abdominal, pelvic and orthopaedic operations, but may be supplemented with two 750 mg (I.M.) doses every 8 hours for up to 24 to 48 hours depending upon procedure.

In total joint replacement, 1.5 g cefuroxime powder may be mixed dry with each pack of methyl methacrylate cement polymer before adding the liquid monomer.

Patients with renal function impairment may require a reduction in dose or frequency of dosing.

**Sequential therapy:**

**Pneumonia:** 1.5 g twice daily (I.V.) for 48-72 hours, followed by 500 mg twice daily Cefuroxime axetil tablet oral therapy for 7 days.

**Acute exacerbations of chronic bronchitis:** 750 mg twice daily (I.V. or I.M.) for 48-72 hours, followed by 500 mg twice daily Cefuroxime axetil tablet oral therapy for 5-7 days.

Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.

**PREPARATION AND DIRECTION FOR USE**

**I.M. (Intramuscular) administration constitution:**

| Vial Dosage Size | Amount of Sterile Water for Injection to be Added |
|---|---|
| 750 mg | 3.0 mL |
| 1.5 g | Not recommended for I.M. administration |

**I.V. (Intravenous) administration constitution as below:**

| Vial Dosage Size | Amount of Sterile Water for Injection to be Added |
|---|---|
| 750 mg | 6.0 mL |
| 1.5 g | 15.0 mL |

The resulting solution should be further diluted in 50 mL to 100 mL of suitable diluents and administered over period of 30 minutes.

**COMPATIBILITY AND STABILITY**

After reconstitution, I.M. and I.V. solutions retain their potency for up to 16 hours at 25°C or for 48 hours if refrigerated at 2°C to 8°C.

The information given here is limited. For further information consult your doctor or pharmacist.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

**Caution**

Foods, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription.

Storage : Powder - Store at temperatures not exceeding 30°C. Protect from light and moisture.
Reconstituted solution - The reconstituted solution is stable for 16 hours at 25°C or for 48 hours in refrigerator (2°C to 8°C). Protect from light.

Availability : 1 pack contains 750 mg vial + 1 ampoule water for injection 10 mL.
1 pack contains 1.5 g vial + 2 ampoules water for injection 10 mL.

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