

# Roxim-AL

(Cefuroxime axetil 500 mg)

## Each Tablet Contains:

Cefuroxime axetil..... 500 mg

Excipients.....Qs

## Clinical Pharmacology:

Cefuroxime axetil:- Cefuroxime axetil is a prodrug of cefuroxime, a second-generation cephalosporin antibiotic. It exerts its antibacterial effects by inhibiting bacterial cell wall synthesis. This occurs through binding to penicillin-binding proteins (PBPs), which are essential for the synthesis and maintenance of the bacterial cell wall, leading to cell lysis and death.

**Indications:** Cefuroxime axetil is indicated for the treatment of various infections, including:

- Respiratory tract infections (e.g., pneumonia, bronchitis)
- Skin and soft tissue infections
- Urinary tract infections
- Lyme disease

## Contraindications:

- **Hypersensitivity:** Contraindicated in individuals with a known allergy to cefuroxime, other cephalosporins, or any components of the formulation.
- **Severe Allergic Reactions:** Patients with a history of severe allergic reactions (e.g., anaphylaxis) to penicillins or other beta-lactam antibiotics should use cefuroxime with caution, as cross-reactivity may occur.
- **Gastrointestinal Conditions:** Contraindicated in patients with a history of gastrointestinal disease, particularly colitis, as antibiotic use can exacerbate such conditions.
- **Renal Impairment:** Caution is advised in patients with severe renal impairment, as dosing adjustments may be necessary.

## Precautions and Warnings:

### Precautions:

1. **Hypersensitivity Reactions:** Monitor for signs of allergic reactions, especially in patients with a history of allergies to penicillins or other beta-lactam antibiotics. Discontinue use if an allergic reaction occurs.
2. **Renal Function:** Use with caution in patients with renal impairment. Dose adjustments may be necessary to avoid accumulation and toxicity.

3. **Gastrointestinal Conditions:** Caution is advised in patients with a history of gastrointestinal diseases, particularly colitis, as antibiotic use may precipitate Clostridium difficile-associated diarrhea.

*Superinfection: Prolonged use may result in overgrowth of non-susceptible*

#### **Warnings:**

1. **Severe Reactions:** Serious hypersensitivity reactions, including anaphylaxis, can occur. Immediate medical attention is required if such reactions are suspected.
2. **Hematologic Reactions:** Rare cases of blood dyscrasias (e.g., thrombocytopenia, leukopenia) have been reported. Monitor complete blood counts in patients on prolonged therapy.
3. **Liver Function:** Caution in patients with liver impairment, as it may affect the metabolism and excretion of the drug
4. organisms (e.g., fungi, resistant bacteria). Monitor for signs of superinfection.

#### **Drug Interactions:**

##### **Anticoagulants:**

**Warfarin:** Cefuroxime may enhance the anticoagulant effect of warfarin, increasing the risk of bleeding. Monitor INR levels closely.

##### **Probenecid:**

Probenecid can decrease the renal excretion of cefuroxime, potentially leading to increased plasma levels. Adjustments in dosing may be required.

##### **Aminoglycosides:**

The combination of cefuroxime with aminoglycosides can increase the risk of nephrotoxicity. Monitor renal function closely when these are used together.

##### **Diuretics:**

Loop diuretics (e.g., furosemide) may increase the risk of nephrotoxicity when used with cefuroxime. Caution is advised.

##### **Other Antibiotics:**

Concurrent use with other antibiotics may affect efficacy, particularly when combining bactericidal and bacteriostatic agents.

##### **Live Vaccines:**

Antibiotics like cefuroxime may reduce the effectiveness of live bacterial vaccines. Consider timing of administration

#### **Adverse Effects:**

- **Common:** Nausea, diarrhea, vomiting, abdominal pain.
- **Allergic:** Rash, itching.
- **Serious:** Anaphylaxis, severe skin reactions.

- **Gastrointestinal:** C. difficile-associated diarrhea.
- **Hematologic:** Thrombocytopenia, leukopenia.
- **Renal:** Nephrotoxicity.
- **Liver:** Elevated liver enzymes.

**Overdosage:**

**Symptoms:**

- Gastrointestinal disturbances: Nausea, vomiting, diarrhea.
- Central nervous system effects: Dizziness, headache.
- Allergic reactions: Rash or itching.

**Management:**

1. **Seek Medical Attention:** Immediate medical evaluation is essential.
2. **Supportive Care:** Treat symptoms as needed.
3. **Monitoring:** Observe for signs of toxicity and renal function.
4. **No Specific Antidote:** Management is primarily supportive.

**Route of Administration:** Oral

**Dosage:** As directed by a physician.

**Storage:** Store in a cool, dry place below 25°C. Protect from light and moisture. Keep out of reach of children.

**Presentation:** It is available as 10x10 tablets



PNBS  
**ALPENA PHARMACEUTICALS PVT. LTD.**

Serve Better, Serve Mankind