

Rx

Cefpirome & Sulbactam for Injection 1.5gm

Cefeprik-  1.5

FOR IM/IV USE

Composition:

Each vial contains:

Cefpirome Sulphate (Sterile) IP

Eq. to Anhydrous Cefpirome 1000 mg

Sulbactam Sodium (Sterile) IP

Eq. to Anhydrous Sulbactam 500 mg

Description:

(Cefpirome Sulphate & Sulbactam) is an injectable antibacterial combination product consisting of the parenteral fourth generation cephalosporin; Cefpirome sulphate & the Beta lactamase inhibitor Sulbactam Sodium.

Cefpirome Sulphate is the Sulphatam of cefpirome, a semisynthetic, broad-spectrum, fourth-generation cephalosporin with antibacterial activity for intravenous administration; it belongs to Peptidoglycan synthesis inhibitor. Cefpirome binds to and inactivates penicillin-binding proteins (PBPs) located on the inner membrane of the bacterial cell wall.

Based on mechanism of action it is classified in Antibiotic, Cephalosporin pharmacological group.

Cefpirome is an off-white to pale yellow powder Freely soluble in water.

Molecular Formula: $C_{22}H_{26}N_2O_8S_2$ **Molecular Weight:** 612.647 g/mol

Sulbactam Sodium is Beta Lactamase inhibitor which inhibit the enzyme Beta lactamase produced by bacteria which

inhibits/destroys the antibiotics. Sulbactam sodium is a derivative of the basic penicillin nucleus. Its molecular formula is

Molecular Formula: $C_8H_{10}N_2O_4S$ **Molecular Weight:** 255.22 g/mol**Mechanism of Action.**

Cefpirome is a semisynthetic, broad-spectrum, fourth-generation cephalosporin with antibacterial activity. Cefpirome binds to and inactivates penicillin-binding proteins (PBPs) located on the inner membrane of the bacterial cell wall. PBPs are enzymes involved in the terminal stages of assembling the bacterial cell wall and in reshaping the cell wall during growth and division. Inactivation of PBPs interferes with the cross-linkage of peptidoglycan chains necessary for bacterial cell wall strength and rigidity. This results in the weakening of the bacterial cell wall and causes cell lysis.

Cefpirome is considered highly active against Gram-negative bacteria, including *Pseudomonas aeruginosa*, and Gram-positive bacteria.

Sulbactam Sodium is a beta-lactamase inhibitor, irreversibly binds to beta-lactamase at or near its active site, thus restores the Cefpirome activity against beta-lactamases producing strains and extending the spectrum activity of Cefpirome.

Pharmacodynamics

Cefpirome sulphate is a cephalosporin beta-lactam antibiotic used in the treatment of bacterial infections caused by susceptible, usually gram-positive organisms. Sulbactam is a semi-synthetic beta lactamase inhibitor. The beta-lactam ring of sulbactam irreversibly binds to beta-lactamase at or near its active site, thereby blocking enzyme activity and preventing metabolism of other beta-lactam antibiotics by the enzyme. When combined with agent with a beta lactamase susceptible antibiotic, such as penicillin's or cephalosporin, to treat infections caused by beta-lactamas producing organisms, results in a decreased turnover rate of this beta-lactamase sensitive antibiotic and enhances its antibacterial activity.

Pharmacokinetics

Volume of distribution is found to be 16.5 liters and plasma protein binding is 8.2-11.7%.

Plasma half-life is 1.4-2.3 hr.

Distribution: Widely distributed into body tissues and fluids; enter breast milk.

Excretion: Mainly by the kidneys via the urine (80-90% unchanged); significantly removed by haemodialysis; 2 hrs (elimination half-life); prolonged in renal impairment.

Indications

Cefpirome is primarily indicated in conditions like Bacteremia, Lower respiratory tract infections, Pneumonia, Promyelocytic leukemia Septicaemia, Severe infections including bacteraemia anisepsicaemia and infections in neutropenic patients, Skin infections Soft tissue infections, Urinary tract infection.

Cefpirome's dosage details are as follows:**Intravenous**

Susceptible infections Adult: As sulfate: 1-2 g every 12 hr via IV inj over 3-5 minutes of infuse over 20-30 minutes.

Dose	Frequency	Route	Instructions
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Adult Dosage

1 to 2 g	12 hourly	IV	
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Pediatric Dosage (20 Kg)

			Not recommended in this age group
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Neonatal Dosage (3kg)

			Not recommended in this age group
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Renal impairment: Loading dose:

1-2 g followed by a maintenance dose adjusted according to CrCl.

CrCl (ml/min)	Dosage Recommendation
20-50	0.5-1 g bid, 0.5-1 g bid.
5-20	0.5-1 g once daily.
<5 (in haemodialysis patients)	<5 (in haemodialysis patients) 0.5 or 1 g once daily with half-dose after each dialysis session.

Contraindications: Hypersensitivity; porphyria.

Special Precautions Allergy to penicillin or to cephalosporins; renal impairment, monitor renal and haematological status;

Prolonged use of Cefpirome sulphate or may lead to fungi overgrowth. Never use this medication for longer than you have been

prescribed. If after a few days use you notice no change in your condition, inform your physician.

Dosage and Administration:

This medication should normally be administered by a healthcare professional. Dosage will vary depending on the patient and the

condition being treated. As an example, the typical dosage for patients with urinary tract infection is 1gm, 2 times a day. Dosage

when treated lower respiratory tract infection may be higher, at 1gm to 2gm.

Side Effects:

The severe or irreversible adverse effects of Cefpirome, which give rise to further complications include Thrombocytopenia, Hemolytic anemia, Hemolytic anemia, Granulocytopenia, Eosinophilia, Agranulocytosis, Elevated hepatic enzymes, Superinfection.

Cefpirome produces potentially life-threatening effects which include Anaphylaxis. which are responsible for the discontinuation of Cefpirome therapy.

The symptomatic adverse reactions produced by Cefpirome are more or less tolerable and if they become severe, they can be treated symptomatically, these include Nausea, Vomiting, Abdominal pain, Rashs, Urticaria, Pseudomembranous colitis, Increase in liver enzymes.

Precautions:

Do not use this medication if you are pregnant, trying to conceive a child, or breast feeding.

overgrowth. Never use this medication for longer than you have been prescribed.

Warning/Precautions:

Cefpirome should be used with caution in patients with impaired kidney or liver function.

Appropriate measure should be taken if secondary infection occurs.

Contraindications:

Hypersensitivity to cephalosporins, penicillins Concomitant live bacterial vaccines.

Pregnancy & Lactation**Pregnancy Category: C**

Lactation: excreted in breast milk; unsure if safe; do not use

Pregnancy Categories

A: Generally acceptable. Controlled studies in pregnant women show no evidence of fetal risk.

B: May be acceptable. Either animal studies show no risk but human studies not available or animal studies showed minor risks and human studies done and showed no risk.

C: Use with caution if benefits outweigh risks. Animal studies show risk and human studies not available or neither animal nor human studies done.

D: Use in LIFE-THREATENING emergencies when no safer drug available. Positive evidence of human fetal risk.

E: Do not use in pregnancy. Risks involved outweigh potential benefits. Safer alternatives exist.

Storage Conditions:

Storage: Store below 30° C. Protect from light

Keep out of reach of children.

Manufactured by: Protech Telelinks
(A WHO-GMP Certified Co.)
Mauza Ogli, Suketi Road, Kala Amb,
District Sirmour (H.P.)173030



Marketed by:

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