Bosch

For Medical Professional only

# Zecef

(Cefuroxime axetil)

**Tablets**
125mg, 250mg
**Suspension**
125mg / 5ml

# زیسیف

ٹیبلیٹس / سسپینشن

(سیفیوروکسم ایگزٹل)

**DESCRIPTION:**
Zecef tablets/suspension contain cefuroxime as cefuroxime axetil. The chemical name of cefuroxime axetil (1-(acetyloxy) ethyl ester of cefuroxime) is (RS)-1-hydroxyethyl (6R,7R)-7-[2-(2-furyl)glyoxyl-amido]-3-(hydroxymethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]-oct-2-ene-2-carboxylate, $7^2$-(Z)-(O-methyl-oxime), 1-acetate 3-carbamate. Its molecular formula is $C_{20}H_{22}N_4O_{10}S$, and it has a molecular weight of 510.48.

**COMPOSITION:**
**Zecef Suspension 125mg/5ml**
When reconstituted as directed, each 5 mL contains:125 mg Cefuroxime as Cefuroxime axetil U.S.P.
(Product Specs.: U.S.P.)

**Zecef Tablets 125mg**
**Each Film coated tablet contains:**
Cefuroxime ...125 mg as Cefuroxime Axetil U.S.P.
(Product Specs.: U.S.P.)

**Zecef Tablet 250mg**
**Each Film coated tablet contains:**
Cefuroxime ...250 mg as Cefuroxime Axetil U.S.P.
(Product Specs.: U.S.P.)

**CLINICAL PHARMACOLOGY:**
**Pharmacodynamic Properties:**
Pharmacotherapeutic group: antibacterials for systemic use, second-generation cephalosporins, ATC-Code: J01DC02

**Mechanism of action:**
Cefuroxime axetil is a semisynthetic, broad-spectrum cephalosporin antibiotic for oral administration. Cefuroxime axetil is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Cefuroxime axetil has activity in the presence of some βeta-lactamase, both penicillinases and cephalosporinases, of gram-negative and gram-positive bacteria.

**Microbiology:**
Cefuroxime axetil has been shown to be active against most isolates of the following bacteria, both in vitro and in clinical infections:
**Aerobic Bacteria:**
**Gram-positive bacteria**
- Staphylococcus aureus (methicillin-susceptible isolates only)
- Streptococcus pneumoniae
- Streptococcus pyogenes

**Gram-negative bacteria**
- Escherichia coli
- Klebsiella pneumoniae
- Haemophilus influenzae
- Haemophilus parainfluenzae
- Moraxella catarrhalis
- Neisseria gonorrhoeae

Most extended spectrum Beta-lactamase (ESBL)-producing and carbapenemase -producing isolates are resistant to cefuroxime axetil.
Spirochetes
- Borrelia burgdorferi

**Aerobic Bacteria:**
**Gram-positive bacteria**
- Staphylococcus epidermidis (methicillin-susceptible isolates only)
- Staphylococcus saprophyticus (methicillin-susceptible isolates only)
- Streptococcus agalactiae

**Gram-negative bacteria**
- Morganella morganii
- Proteus inconstans
- Proteus mirabilis
- Providencia rettgeri

**Anaerobic Bacteria:**
**Gram-positive bacteria**
- Peptococcus niger

**PHARMACOKINETIC PROPERTIES:**
**Absorption**
After oral administration, cefuroxime axetil is absorbed from the gastrointestinal tract and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa and blood to cefuroxime.
Effect of Food: Absorption of the tablet is greater when taken after food (absolute bioavailability increases from 37% to 52%).

**Distribution**
Cefuroxime is distributed throughout the extracellular fluids. Approximately 50% of serum cefuroxime is bound to protein.

**Biotransformation**
The axetil moiety is metabolized to acetaldehyde and acetic acid.

**Elimination**
Cefuroxime is excreted unchanged in the urine; in adults, approximately 50% of the administered dose is recovered in the urine within 12 hours. The pharmacokinetics of cefuroxime in pediatric subjects have not been studied. Until further data are available, the renal elimination of cefuroxime axetil established in adults should not be extrapolated to pediatric subjects.

**THERAPEUTIC INDICATIONS:**
Cefuroxime axetil is indicated for the treatment of patients with mild to moderate infection listed below.
- Treatment of mild-to-moderate pharyngitis/tonsillitis
- Treatment of acute bacterial otitis media
- Acute bacterial maxillary sinusitis
- Zecef tablets are indicated for the treatment of mild-to-moderate acute bacterial exacerbations of chronic bronchitis
- Uncomplicated skin and skin-structure infections
- Uncomplicated Urinary Tract Infections
- Uncomplicated gonorrhea
- Early lyme disease (erythema migrans)
- Impetigo

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZECEF and other antibacterial drugs, ZECEF should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy.

**DOSAGE AND ADMINISTRATION:**
**Tablets:**
Administer ZECEF tablets as described in the dosage guidelines table below with or without food.
**Table 1. Adult Patients and Pediatric Patients Dosage Guidelines for ZECEF Tablets**

| Infection | Dosage |
|---|---|
| Adults and Adolescents (13 years and older) | |
| Pharyngitis/tonsillitis (mild to moderate) | 250 mg every 12 hours |
| Acute bacterial maxillary sinusitis (mild to moderate) | 250 mg every 12 hours |
| Acute bacterial exacerbations of chronic bronchitis (mild to moderate) | 250 or 500 mg every 12 hours |
| Uncomplicated skin and skin -structure infections | 250 or 500 mg every 12 hours |
| Uncomplicated urinary tract infections | 250 mg every 12 hours |
| Uncomplicated gonorrhea | 1,000 mg |
| Early Lyme disease | 500 mg every 12 hours |
| Pediatric Patients younger than 13 years | |
| Acute bacterial otitis media | 250 mg every 12 hours |
| Acute bacterial maxillary sinusitis | 250 mg every 12 hours |

The safety and effectiveness of ZECEF administered for less than 10 days in patients with acute exacerbations of chronic bronchitis have not been established.

**Suspension:**
Administer ZECEF for oral suspension as described in the dosage guidelines table below with food.

**Table 2. Pediatric Patients (3 Months to 12 Years) Dosage Guidelines for ZECEF for Oral Suspension**

| Infection | Recommended Daily Dose | Maximum Daily Dose |
|---|---|---|
| Pharyngitis/tonsillitis | 20 mg/kg | 500 mg |
| Acute bacterial otitis media | 30 mg/kg | 1,000 mg |
| Acute bacterial maxillary sinusitis | 30 mg/kg | 1,000 mg |
| Impetigo | 30 mg/kg | 1,000 mg |

Recommended daily dose given twice daily divided in equal doses.
**Dosage in Patients with Impaired Renal Function**
A dosage interval adjustment is required for patients whose creatinine clearance is less than 30 mL/min.

**Table 3. Dosing in Adults with Renal Impairment**

| Creatinine Clearance (mL/min) | Recommended Dosage |
|---|---|
| ≥30 | No dosage adjustment |
| 10 to <30 | Standard individual dose given every 24 hours |
| <10 (without hemodialysis) | Standard individual dose given every 48 hours |
| Hemodialysis | A single additional standard dose should be given at the end of each dialysis |

**CONTRAINDICATIONS:**
ZECEF is contraindicated in patients with a known hypersensitivity (e.g., anaphylaxis) to ZECEF or to other β-lactam antibacterial drugs (e.g., penicillins and cephalosporins).

**WARNINGS AND PRECAUTIONS:**
**Anaphylactic Reactions**
Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on β-lactam antibacterials, including ZECEF. These reactions are more likely to occur in individuals with a history of β-lactam hypersensitivity and a history of sensitivity to multiple allergens.

**Clostridium difficile-Associated Diarrhea**
Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including ZECEF, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.

**Potential for Microbial Overgrowth**
The possibility of superinfections with fungal or bacterial pathogens should be considered during therapy.

**Development of Drug-Resistant Bacteria**
Prescribing ZECEF either in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

**Phenylketonuria**
ZECEF for oral suspension 125 mg/5 mL contains phenylalanine 11.8 mg per 5 mL (1 teaspoonful) of reconstituted suspension.

**Interference with Glucose Tests**
A false-positive result for glucose in the urine may occur with copper reduction tests, and a false- negative result for blood/plasma glucose may occur with ferricyanide tests in subjects receiving ZECEF

**DRUG INTERACTIONS:**
**Drugs that Reduce Gastric Acidity**
Drugs that reduce gastric acidity may result in a lower bioavailability of ZECEF compared with administration in the fasting state. Administration of drugs that reduce gastric acidity may negate the food effect of increased absorption of ZECEF when administered in the postprandial state. Administer ZECEF at least 1 hour before or 2 hours after administration of short-acting antacids. Histamine-2 (H2) antagonists and proton pump inhibitors should be avoided.

**Probenecid**
Concomitant administration of probenecid with cefuroxime axetil tablets increases serum concentrations of cefuroxime. Coadministration of probenecid with cefuroxime axetil is not recommended.

**Laboratory Test Interactions**
A false-positive reaction for glucose in the urine may occur with copper reduction tests (e.g.,Benedict's or Fehling's solution), but not with enzyme-based tests for glycosuria.

**PREGNANCY:**
**Pregnancy Category B**
There are no adequate & well-controlled studies in pregnant women. This drug should be used during pregnency only if clearly needed.

**LACTATION:**
Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with cefuroxime axetil.

**Pediatric Use**
The safety and effectiveness of cefuroxime axetil have been established for pediatric patients aged 3 months to 12 years for acute bacterial maxillary sinusitis based upon its approval in adults. Use of cefuroxime axetil in pediatric patients is supported by pharmacokinetic and safety data in adults and pediatric patients.

**Geriatric Use**
Cefuroxime is substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

**ADVERSE EFFECTS:**
**Common:**
Candida overgrowth, eosinophilia, headache, dizziness, diarrhoea, nausea, abdominal pain, transient increases of hepatic enzyme levels.

**Uncommon:**
Positive Coomb's test, thrombocytopenia, leukopenia (sometimes profound), vomiting and skin rashes.

**Rare:**
Clostridium difficile overgrowth, haemolytic anaemia, drug fever, serum sickness, anaphylaxis, Jarisch-Herxheimer reaction, pseudomembranous colitis, jaundice (predominantly cholestatic), hepatitis, urticaria, pruritus, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis) (see Immune system disorders), angioneurotic oedema.

**OVER DOSAGE:**
Overdosage of cephalosporins can cause cerebral irritation leading to convulsions or encephalopathy. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

**Method of Reconstitution:**
Shake well before adding water to loosen the content. Add 20ml cool boiled water through given cup. Shake vigorously after tighten the cap.

**Presentation**
Zecef 125 mg Tablets : Cold Form & Cold Seal Pack of 14's
Zecef 250 mg Tablets : Cold Form & Cold Seal Pack of 14's
Zecef 125 mg / 5ml Suspension (50 ml) in 90 ml Amber Glass Bottle.

**STORAGE:**
**Tablet:**
- Store below 25°C.
- Protect from heat, sunlight & moisture.

**Suspension:**
- Do not take if seal is broken.
- Before reconstitution protect from heat, sunlight & moisture, store below 30°C.
- After reconstitution store in refrigerator 2-8°C (Do not freeze) and used within 10 days.
- Close the bottle properly after use.
- The expiration date refer to the product correctly stored at the required condition.

**Direction:**
- Keep out of the reach of children.
- Patients and healthcare professionals can also report suspected adverse drug reaction at ade@bosch-pharma.com
- To be sold on prescription of a registered medical practitioner only.

## ہدایات برائے استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ٹیبلیٹس: دھوپ، گرمی اور نمی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

سسپینشن: غیر تیار شدہ دوا کو دھوپ، گرمی اور نمی سے محفوظ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

تیار شدہ دوا ریفریجریٹر میں ۲۔۸ ڈگری سینٹی گریڈ پر رکھیں (جمنے نہ دیں)

اور ۱۰ روز میں استعمال کرلیں۔ استعمال کے بعد ڈھکن کو اچھی طرح بند رکھیں۔

بچوں کی پہنچ سے دُور رکھیں۔

صرف مستند ڈاکٹر کے نسخے پر فروخت کے لئے۔

Manufactured by:
**Bosch Pharmaceuticals (Pvt) Ltd.**
221-223, Sector 23, Korangi Industrial Area,
Karachi - Pakistan

ISO 9001:2015 Certified Company

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FIRST & ONLY CERTIFIED HALAAL

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PHARMACEUTICAL COMPANY