正面

Revised: May, 2023

Rx only

CEFUROXIME AXETIL-ZHIJUN

Cefuroxime Axetil Tablets 250 mg

DESCRIPTION
Cefuroxime Axetil-Zhijun are white, capsule-shaped, film-coated tablets engraved with "DLX" on one side and plain on the other side.
Each tablet contains 250 mg cefuroxime as cefuroxime axetil.

PHARMACODYNAMICS
Cefuroxime axetil is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most β-lactamases and is active against a wide range of gram-positive and gram-negative organisms.
Microbiology: Cefuroxime axetil owes its *in vivo* bactericidal activity to the parent compound, cefuroxime. Cefuroxime is a well-characterized and effective antibacterial agent which has broad-spectrum bactericidal activity against a wide range of common pathogens, including β-lactamase-producing strains.
Cefuroxime has good stability to bacterial β-lactamase and consequently, is active against many ampicillin-resistant or amoxicillin-resistant strains. The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.
Cefuroxime is usually active against the following organisms *in vitro*:
Aerobes, Gram-Negative: *Haemophilus influenzae* (including ampicillin-resistant strains); *Haemophilus parainfluenzae*; *Moraxella catarrhalis*; *Escherichia coli*; *Klebsiella* species; *Proteus mirabilis*; *Proteus inconstans*; *Providencia* species; *Proteus rettgeri* and *Neisseria gonorrhoeae* (including penicillinase- and non-penicillinase- producing strains).
Some strains of *Morganella morganii,* Enterobacter species and Citrobacter species have been shown by *in vitro* tests to be resistant to cefuroxime and other β-lactam antibiotics.
Aerobes, Gram-Positive: *Staphylococcus aureus* and *Staphylococcus epidermidis* (including penicillinase-producing strains but excluding methicillin-resistant strains), *Streptococcus pyogenes* (and other β-haemolytic streptococci), *Streptococcus pneumoniae*, *Streptococcus* Group B (*Streptococcus agalactiae*) and Propionibacterium species. Certain strains of enterococci, eg. *Streptococcus faecalis,* are resistant.
Anaerobes, Gram-positive and Gram-negative cocci (including *Peptococcus* and *Peptostreptococcus* spp); Gram-positive bacilli (including *Clostridium* species) and Gram-negative bacilli (including *Bacteroides* and *Fusobacterium* species); Most strains of *Bacteroides fragilis* are resistant.
Other Organisms: *Borrelia burgdorferi*.
Pseudomonas species, and *Campylobacter* species, *Acinetobacter calcoaceticus*, *Listeria monocytogenes*, *Legionella* species and most strains of *Serratia* and *Proteus vulgaris* and *Clostridium difficile* are resistant to many cephalosporins including cefuroxime.

PHARMACOKINETICS
After oral administration, cefuroxime axetil is absorbed from the gastro-intestinal tract and rapidly hydrolysed in the intestinal mucosa and blood to release cefuroxime into the circulation.
Optimum absorption occurs when it is administered after a meal.
Peak serum cefuroxime levels occur approximately two to three hours after oral dosing. The serum half life is about 1.2 hours. Approximately 50% of serum cefuroxime is protein bound.
Cefuroxime is not metabolized and is excreted by glomerular filtration and tubular secretion. Concurrent administration of probenecid increases the area under the mean serum concentration time curve by 50%.

INDICATIONS
Cefuroxime axetil is indicated for the treatment of infections caused by sensitive bacteria.
Upper respiratory tract infections eg, ear, nose and throat infections ie, otitis media, sinusitis, tonsillitis and pharyngitis.
Lower respiratory tract infections eg, pneumonia, acute bronchitis and acute exacerbations of chronic bronchitis.
Genito-urinary tract infections eg, pyelonephritis, cystitis and urethritis.
Skin and soft-tissue infections eg, furunculosis, pyoderma and impetigo.
Gonorrhoea, acute uncomplicated gonococcal urethritis and cervicitis.
Cefuroxime is also available as the sodium salt (cefuroxime sodium) for parenteral administration. This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated.
Where appropriate, Cefuroxime Axetil Tablet is effective when used following initial parenteral administration of cefuroxime sodium in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

DOSAGE & ADMINISTRATION
Route of administration: Oral
Dosage in adults
Most infections will respond to 250mg bd. In mild to moderate lower respiratory tract infections e.g. bronchitis 250mg bd should be given. For more severe lower respiratory tract infections, or if pneumonia is suspected then 500mg bd should be given. For urinary tract infections a dose of 125mg bd is usually adequate; in pyelonephritis the recommended dose is 250mg bd. A single dose of one gram is recommended for the treatment of uncomplicated gonorrhoea.
Sequential therapy:
Pneumonia:
1.5g Cefuroxime Sodium bd (iv or im) for 48-72 hours, followed by 500mg bd cefuroxime axetil oral therapy for 7 days.
Acute exacerbations of chronic bronchitis:
750mg Cefuroxime Sodium bd (iv or im) for 48-72 hours, followed by 500mg bd cefuroxime axetil 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.
Dosage in children
The usual dose is 125mg bd or 10mg/kg bd to a maximum of 250mg daily. For otitis media, in children less than 2 years of age the usual dosage is 125mg bd or 10mg/kg bd to a maximum of 250mg daily and in children over 2 years of age, 250mg bd or 15mg/kg bd to a maximum of 500mg daily. There is no experience in children under 3 months of age.
Cefuroxime Axetil Tablets should not be crushed and are therefore, unsuitable for treatment of patients eg, younger children, who cannot swallow tablets.

The usual course of therapy is seven days.
Cefuroxime Axetil Tablet should be taken after food for optimum absorption.

CONTRAINDICATIONS
Hypersensitivity to cephalosporin antibiotics.

背面

WARNINGS AND PRECAUTIONS
Special care is indicated in patients who have experienced an allergic reaction to penicillins or other β-lactams.
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Cefuroxime Axetil-Zhijun, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Cefuroxime Axetil-Zhijun must be discontinued immediately and appropriate alternative therapy instituted.
As with other antibiotics, use of cefuroxime axetil may result in the overgrowth of Candida. Prolonged use may also result in the overgrowth of non-susceptible organisms (e.g. Enterococci and *Clostridium difficile*), which may require interruption of treatment.
Pseudomembranous colitis has been reported with the use of broad-spectrum antibiotics, therefore, it is important to consider its diagnosis in patients who develop serious diarrhoea during or after antibiotic use.
With a sequential therapy regime the timing of change to oral therapy is determined by severity of the infection, clinical status of the patient and susceptibility of the pathogens involved. The change to oral therapy should only be made once there is a clear clinical improvement. If there has been no clinical improvement after 72 hours of parenteral treatment, then the patient's treatment should be reviewed. Please refer to the relevant prescribing information for cefuroxime sodium before initiating sequential therapy.
Drug interactions
In common with other antibiotics, cefuroxime axetil may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.
As a false negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving cefuroxime axetil. This antibiotic does not interfere in the alkaline picrate assay for creatinine.
Concurrent administration of probenecid increases the area under the mean serum concentration time curve by 50%. Serum levels of cefuroxime are reduced by dialysis.
A positive Coomb's test has been reported during treatment with cephalosporins. This phenomenon can interfere with cross matching of blood.
Pregnancy
There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime axetil but, as with all drugs, it should be administered with caution during early months of pregnancy.
Lactation
Cefuroxime is excreted in human milk, and consequently caution should be exercised when cefuroxime axetil is administered to a nursing mother.

ADVERSE EFFECTS
Adverse drug reactions to cefuroxime axetil are generally mild and transient in nature.
The following convention has been used for the classification of frequency:
very common(≥ 1/10), common (≥1/100, <1/10), uncommon(≥1/1000, <1/100), rare(≥1/10,000, <1/1000,) very rare (<1/10,000).
Infections and infestations
Common: Candida overgrowth
Blood and lymphatic system disorders
Common: Eosinophilia
Uncommon: Positive Coombs' test, thrombocytopenia, leucopenia (sometimes profound)
Very rare: Haemolytic anaemia
Cephalosporins as a class tend to be absorbed onto the surface of red cells membranes and react with antibodies directed against the drug to produce a positive Coombs' test (which can interfere with cross-matching of blood) and very rarely haemolytic anaemia.
Immune system disorders
Hypersensitivity reactions including
Uncommon: Skin rashes
Rare: Urticaria, pruritus
Very rare: Drug fever, serum sickness, anaphylaxis
Nervous system disorders
Common: Headache, dizziness
Gastrointestinal disorders
Common: Gastrointestinal disturbances including diarrhoea, nausea, abdominal pain
Uncommon: Vomiting
Rare: Pseudomembranous colitis
Hepatobiliary disorders
Common: Transient increases of hepatic enzyme levels, [ALT (SGPT), AST (SGOT), LDH]
Very rare: Jaundice (predominantly cholestatic), hepatitis
Skin and subcutaneous tissue disorders
Very rare: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic necrolysis)

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

STORAGE CONDITION
Store below 30℃

PACKAGING
6 tablets/blister, 2 blisters/carton or 10 blisters/carton

SINOPHARM

Manufactured by:
SINOPHARM ZHIJUN (SHENZHEN) PHARMACEUTICAL CO., LTD.
No.16, Lanqing Yilu ,Hi-tech Zone, Guanlan,
Longhua New District, Shenzhen, China

名称	头孢呋辛酯片说明书—马来西亚		
规格	通用	版本号	05
尺寸	143×205mm	设计	武广利
注册审核/日期		年 月 日	