

# Winfax<sup>®</sup>

## Cefuroxime USP

### Composition:

**Winfax<sup>®</sup> 250 mg tablet:** Each film coated tablet contains Cefuroxime axetil USP equivalent to Cefuroxime 250 mg.

**Winfax<sup>®</sup> 500 mg tablet:** Each film coated tablet contains Cefuroxime axetil USP equivalent to Cefuroxime 500 mg

**Winfax<sup>®</sup> Powder for suspension (70ml) :** Each 5 ml reconstituted suspension contains Cefuroxime axetil USP equivalent to Cefuroxime 125 mg

### Pharmacology:

**Winfax<sup>®</sup>** (Cefuroxime) is a well-characterized and effective antibacterial agent, Cefuroxime is one of the bactericidal second generation cephalosporin antibiotic which is active against a wide range of Gram-positive and Gram-negative susceptible organisms, including  $\beta$ -lactamase producing strains. Cefuroxime has good stability to bacterial  $\beta$ -lactamase and consequently, is active against many ampicillin-resistant and amoxicillin-resistant strains. It is indicated for the treatment of infections caused by sensitive bacteria. Cefuroxime should be taken after food for optimum absorption.

### Indication:

**Winfax<sup>®</sup>** (Cefuroxime) is indicated in the treatment of:

1. Upper respiratory tract infections: for example, ear, nose and throat infections such as otitis media, sinusitis, tonsillitis and pharyngitis. 2. Lower respiratory tract infections: for example, acute bronchitis, acute exacerbations of chronic bronchitis and pneumonia. 3. Skin and soft tissue infections: such as furunculosis, pyoderma, and impetigo. 4. Genito-urinary tract infections: such as pyelonephritis, urethritis, and cystitis. 5. Gonorrhoea: acute uncomplicated gonococcal urethritis, and cervicitis. 6. Early Lyme disease & subsequent prevention of late Lyme disease.

### Dosage & Administration:

Oral : Tablet

(May be administered without regard to meals) Adolescents & adults(13 years & above) Pharyngitis or Tonsillitis: 250 mg twice daily 5-10 days Acute bacterial maxillary sinusitis: 250 mg twice daily 10 days. Acute bacterial exacerbation of chronic bronchitis: 250-500 mg twice daily 10 days. Secondary bacterial infections of acute bronchitis: 250-500 mg twice daily 5-10 days. Uncomplicated skin & skin-structure infections: 250-500 mg twice daily 10 days. Uncomplicated urinary tract infection: 125-250 mg twice daily 7-10 days. Uncomplicated gonorrhoea: 1000 mg single dose. Lyme disease: 500 mg twice daily 20 days. Paediatric patients (Upto12 years). Pharyngitis or Tonsillitis: 125 mg twice daily 5-10 days. Acute otitis media: 250 mg twice daily 10 days. Acute bacterial maxillary sinusitis: 250 mg twice daily 10 days. Suspension (Must be administered with food. Shake the bottle well before each use) Paediatric patients (3 months to 12 years). Pharyngitis or Tonsillitis: 20 mg/kg/day in two divided doses 5-10 days. Acute otitis media: 30 mg/kg/day in two divided doses 10 days. Acute bacterial maxillary sinusitis: 30 mg/kg/day in two divided doses 10 days. Cefuroxime should be taken after food for optimum absorption.

### Direction For Reconstitution Of Suspension:

Shake the bottle well before adding water. Then add 37 ml of boiled and cooled water (with the help of the provided cup) to the bottle. For proper mixing add approximately half of total amount of water and shake well. Add remainder of water and shake again. Then continue shaking the bottle until the powder is dissolved properly. Do not use reconstituted suspension more than 10 days.

### Contraindication:

Patients with known allergy to cephalosporins & pseudomembranous colitis are contraindicated.

### Side Effect:

Generally Cefuroxime is well tolerated. However, a few side effects like nausea, vomiting, diarrhea, abdominal discomfort or pain may occur. As with other broad-spectrum antibiotics, prolonged administration of Cefuroxime may result in overgrowth of nonsusceptible microorganisms. Rarely (<0.2%) renal dysfunction, anaphylaxis, angioedema, pruritis, rash and serum sickness like urticaria may appear.

### Acute Overdosage:

Excessively large doses of all Cephalosporins can cause cerebral irritation and may cause convulsions. This complication is unlikely to occur in routine practice unless the patient is in renal failure. Hemodialysis or peritoneal dialysis can remove Cefuroxime.

### Precaution:

As with other antibiotics, prolonged use of Cefuroxime may result in the over growth of nonsusceptible organisms (e.g. Candida, Enterococci, Clostridium difficile), which may require interruption of treatment.

### Use In Pregnancy & Lactation:

While all antibiotics should be avoided in the first trimester if possible, Cefuroxime has been safely used in later pregnancy to treat urinary and other infections. The placental transfer of Cefuroxime into the fetus was studied in 20 women and therapeutically active concentrations were found in the serum of infants for up to 6 hours after delivery. Cefuroxime is excreted in human milk, and consequently caution should be exercised when Cefuroxime is administered to a nursing mother.

### Drug Interaction:

Concomitant administration of probenecid with Cefuroxime increases the area under the serum concentration versus time curve by 50%. Drug that reduces gastric acidity may result in a lower bioavailability of Cefuroxime and tend to cancel the effect of postprandial absorption.

### Storage Condition:

**Tablet:** Store below 30° C, protected from light and moisture.

**Suspension:** Store below 25° C, protected from light and moisture.

### Pack Size:

**Winfax<sup>®</sup> 250 mg tablet:** Box containing 3 x 4 tablets in Alu-Alu blister pack.

**Winfax<sup>®</sup> 500 mg tablet:** Box containing 2 x 4 tablets in Alu-Alu blister pack.

**Winfax<sup>®</sup> Powder for suspension (70 ml):** Bottle containing dry powder for reconstitute 70 ml suspension.

### Manufactured by:



**The White Horse Pharmaceuticals Ltd.**

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