# BIOS LAB PRIVATE LIMITED

## Certificate of Analysis -COA

| | | | |
|---|---|---|---|
| **Product Name:** | **TILCEF-250** | Report No.: | FPB-2310012 |
| Generic Name: | Cefuroxime Axetil Tablets IP 250 mg | | |
| Batch No: | BT300153 | Batch Size: | 50,000Tablets |
| Mfg Date: | 09-2023 | Exp. Date: | 08-2025 |
| Date of analysis: | 06-10-2023 | Date of release: | 07-10-2023 |
| Sample Quantity: | 60 Tablets | | |

| Test Parameters | Specification | Observation |
|---|---|---|
| **Description** | Off-white coloured, round shaped, biconvex film coated tablet having score on one side and plain on other side. | Off-white coloured, round shaped, biconvex film coated tablet having score on one side and plain on other side. |
| **Identification** | | |
| A.By-IR | Compare the spectrum with that obtained with cefuroxime axetil RS or with the reference spectrum of cefuroxime axetil. | complies |
| B. By-HPLC | In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peaks due to diastereomer A and B in the chromatogram obtained with reference solution (c). | Complies |
| **Average weight** | 415 mg ± 3.0 % | 406.0 mg |
| **Uniformity of average weight** | ± 5.0 % of the average weight | Min: -3.15%, Max: +3.07% |
| **Dissolution Test** | NLT 70% (Q) | Min:78.2%, Max: 86.2%, Avg:81.8% |
| **Related Substances** | | |
| E-isomers | NMT 1.5 % | complies |
| $D^3$-isomers | NMT 2.0 % | complies |
| The area of any other secondary peak | NMT 1.0 % | complies |
| **Assay: Each film coated tablet contains** | | |
| Cefuroxime Axetil IP<br>Eq. to Cefuroxime 250 mg | 225.0 mg to 275.0 mg<br>(90.0% to 110.0%) | 240.3 mg (96.1%) |

**Remarks: -** The above product complies ~~/ does not comply~~ as per IP~~/BP/USP &~~ ~~In House specification~~.

| Particulars | Prepared By | Checked By | Approved By |
|---|---|---|---|
| **Name** | Alpana Patel | Anisha Mishra | Nitesh Kumar |
| **Designation** | Sr.Officer-QC | Sr.Executive-QC | Manager QC |
| **Sign./Date** | 07-10-2023 | 07-10-2023 | 07-10-2023 |

**Product Mfg . By : GNOSIS PHARMACEUTICALS PVT. LTD.**

# BIOS LAB PVT. LTD.

B-8, MILAN COMPLEX, SARKHEJ, AHMEDABAD.

**QUALITY CONTROL DEPARTMENT**

## CERTIFICATE OF ANALYSIS

See Rule 150 E (F) Under The Drugs & Cosmetic Act 1940 and The Rules there under

**Report No. :** **FPG-2202054**

**Sample Name :** **TILCEF™– 250 TABLETS**

**Generic Name :** **Cefuroxime Axetil 250mg Tablets**

| | | | |
|---|---|---|---|
| **Product Name** | **TILCEF™– 250** | **A.R.No.** | FPG-2202054 |
| **Batch No.** | BT10101B | **Batch Size** | 0.25 Lacs Tablets |
| **Mfg. Date** | JAN. 2022 | **Sample Qty.** | 60 Tablets |
| **Exp. Date** | DEC. 2023 | **Test as per** | Manufacturer Specification |
| **Date of Receipt** | 22-01-2022 | **Date of Release** | 24-01-2022 |

| S NO. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1. | Description | Off white, round, biconvex film coated tablets having score on one side and plain on other side. | Off white, round, biconvex film coated tablets having score on one side and plain on other side. |
| 2. | Identification | In the Assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the peaks due to diastereomer A and B in the chromatogram obtained with reference solution | Compiles |
| 3. | Average weight | 415 mg ± 3% | 420.20 mg |
| 4. | Uniformity of average weight | ± 5.0% of average weight | Min= -2.40%, Max= +3.1% |
| 5. | Dissolution Test | NLT 70.0% (D) | Min = 85.9%<br>Max = 100.2%<br>Mean = 93.4% |
| 6. | Related Substance | NMT-1.0% | Compiles |
| 7. | ASSAY: Each film coated tablet contains | | |
| | Cefuroxime Axetil IP<br>Eq. to Cefuroxime 250 mg | 225.00 mg to 275.00 mg<br>(90% to 110%) | 265.70 (106.3%) |

Remarks: The above product compiles as per IP.

*Manufactured by: Gnosis Pharmaceuticals Pvt. Ltd. (HP)

# BIOS LAB PVT. LTD.

B-8, MILAN COMPLEX, SARKHEJ, AHMEDABAD.

**QUALITY CONTROL DEPARTMENT**

## CERTIFICATE OF ANALYSIS

See Rule 150 E (F) Under The Drugs & Cosmetic Act 1940 and The Rules there under

**Report No. :** **FPG-2202053**

**Sample Name :** **TILCEF™– 250 TABLETS**

**Generic Name :** **Cefuroxime Axetil 250mg Tablets**

| | | | |
|---|---|---|---|
| **Product Name** | **TILCEF™– 250** | **A.R.No.** | FPG-2202053 |
| **Batch No.** | BT10189 | **Batch Size** | 0.30 Lacs Tablets |
| **Mfg. Date** | JAN. 2022 | **Sample Qty.** | 60 Tablets |
| **Exp. Date** | DEC. 2023 | **Test as per** | Manufacturer Specification |
| **Date of Receipt** | 14-02-2022 | **Date of Release** | 16-02-2022 |

| S NO. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1. | Description | Off white, round, biconvex film coated tablets having score on one side and plain on other side. | Off white, round, biconvex film coated tablets having score on one side and plain on other side. |
| 2. | Identification | In the Assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the peaks due to diastereomer A and B in the chromatogram obtained with reference solution | Compiles |
| 3. | Average weight | 415 mg ± 3% | 420.20 mg |
| 4. | Uniformity of average weight | ± 5.0% of average weight | Min= -2.20%, Max= +3.1% |
| 5. | Dissolution Test | NLT 70.0% (D) | Min = 84.9%<br>Max = 99.3%<br>Mean = 90.4% |
| 6. | Related Substance | NMT-1.0% | Compiles |
| 7. | ASSAY: Each film coated tablet contains<br>Cefuroxime Axetil IP<br>Eq. to Cefuroxime 250 mg | 225.00 mg to 275.00 mg<br>(90% to 110%) | 259.70 (103.8%) |

Remarks: The above product compiles as per IP.

*Manufactured by: Gnosis Pharmaceuticals Pvt. Ltd. (HP)

# BIOS LAB PVT. LTD.

B-8, MILAN COMPLEX, SARKHEJ, AHMEDABAD.

**QUALITY CONTROL DEPARTMENT**

## CERTIFICATE OF ANALYSIS

See Rule 150 E (F) Under The Drugs & Cosmetic Act 1940 and The Rules there under

**Report No. :** **FPG-2202034**

**Sample Name :** **TILCEF™– 500 TABLETS**

**Generic Name :** **Cefuroxime Axetil 500 mg Tablets**

| | | | |
|---|---|---|---|
| **Product Name** | **TILCEF™– 250** | **A.R.No.** | FPG-2202034 |
| **Batch No.** | BT10082B | **Batch Size** | 0.20 Lacs Tablets |
| **Mfg. Date** | JAN. 2022 | **Sample Qty.** | 60 Tablets |
| **Exp. Date** | DEC. 2023 | **Test as per** | Manufacturer Specification |
| **Date of Receipt** | 10-02-2022 | **Date of Release** | 14-02-2022 |

| S NO. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1. | Description | Off white, round, biconvex film coated tablets having score on one side and plain on other side. | Off white, round, biconvex film coated tablets having score on one side and plain on other side. |
| 2. | Identification | In the Assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the peaks due to diastereomer A and B in the chromatogram obtained with reference solution | Compiles |
| 3. | Average weight | 1020 mg ± 3% | 1015.23 mg |
| 4. | Uniformity of average weight | ± 5.0% of average weight | Min= -2.70%, Max= +2.71% |
| 5. | Dissolution Test | NLT 70.0% (D) | Min = 86.5%<br>Max = 98.2%<br>Mean = 92.4% |
| 6. | Related Substance | NMT-1.0% | Compiles |
| 7. | ASSAY: Each film coated tablet contains<br>Cefuroxime Axetil IP<br>Eq. to Cefuroxime 250 mg | 450.00 mg to 550.00 mg<br>(90% to 110%) | 512.37 (102.5%) |

Remarks: The above product compiles as per IP.

*Manufactured by: Gnosis Pharmaceuticals Pvt. Ltd. (HP)

# BIOS LAB PVT. LTD.

B-8, MILAN COMPLEX, SARKHEJ, AHMEDABAD.

**QUALITY CONTROL DEPARTMENT**

## CERTIFICATE OF ANALYSIS

See Rule 150 E (F) Under The Drugs & Cosmetic Act 1940 and The Rules there under

**Report No. :** **FPG-2112046**

**Sample Name :** **TILCEF™– 500 TABLETS**

**Generic Name :** **Cefuroxime Axetil 500 mg Tablets**

| | | | |
|---|---|---|---|
| **Product Name** | **TILCEF™– 250** | **A.R.No.** | FPG-2112046 |
| **Batch No.** | BT10152 | **Batch Size** | 0.30 Lacs Tablets |
| **Mfg. Date** | NOV. 2021 | **Sample Qty.** | 60 Tablets |
| **Exp. Date** | OCT. 2023 | **Test as per** | Manufacturer Specification |
| **Date of Receipt** | 11-12-2021 | **Date of Release** | 14-12-2021 |

| S NO. | TEST | SPECIFICATION | RESULT |
|---|---|---|---|
| 1. | Description | Off white, round, biconvex film coated tablets having score on one side and plain on other side. | Off white, round, biconvex film coated tablets having score on one side and plain on other side. |
| 2. | Identification | In the Assay, the principal peaks in the chromatogram obtained with the test solution corresponds to the peaks due to diastereomer A and B in the chromatogram obtained with reference solution | Compiles |
| 3. | Average weight | 1020 mg ± 3% | 1018.15 mg |
| 4. | Uniformity of average weight | ± 5.0% of average weight | Min= -2.10%, Max= +2.83% |
| 5. | Dissolution Test | NLT 70.0% (D) | Min = 88.9%<br>Max = 101.2%<br>Mean = 95.4% |
| 6. | Related Substance | NMT-1.0% | Compiles |
| 7. | ASSAY: Each film coated tablet contains | | |
| | Cefuroxime Axetil IP<br>Eq. to Cefuroxime 250 mg | 450.00 mg to 550.00 mg<br>(90% to 110%) | 504.32 (100.9%) |

Remarks: The above product compiles as per IP.

*Manufactured by: Gnosis Pharmaceuticals Pvt. Ltd. (HP)

# TILCEF™– 250/500 TABLETS

**PRODUCTDESCRIPTION**

**TILCEF™ 250mg/500mg Tablet:**

Each film-coated tablet contains,
Cefuroxime Axetil, IP, equivalent to Cefuroxime– 250mg/500mg

**PHARMACOLOGIC PROPERTIES**

**Pharmacodynamics**

Cefuroxime axetil is a semisynthetic, broad-spectrum cephalosporin antibiotic for oral administration. The in vivo bactericidal activity of cefuroxime axetil is due to its binding to essential target proteins and the resultant inhibition of cell-wall synthesis. Cefuroxime is bactericidal against a wide range of common pathogens, including many beta- lactamase–producing strains. It is stable to many bacterial beta-lactamases, especially plasmid-mediated enzymes that are commonly found in Enterobacteriaceae.

Cefuroxime has been demonstrated to be active against most strains of the following microorganisms both in vitro and in clinical infections.

The prevalence of acquired resistance is geographically and time dependent and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

| |
|---|
| In vitro susceptibility of micro-organisms to Cefuroxime<br>Where clinical efficacy of cefuroxime axetil has been demonstrated in clinical trials this is indicated with an asterisk (*). |
| Commonly Susceptible Species |
| <u>Gram-Positive Aerobes:</u><br>*Staphylococcus aureus (methicillin susceptible)**<br>*Coagulase negative staphylococcus (methicillin susceptible) Streptococcus pyogenes**<br>*Beta-hemolytic streptococci* |
| <u>Gram-Negative Aerobes:</u><br>*Haemophilus influenzae* including ampicillin resistant*<br>*strains Haemophilus parainfluenzae**<br>*Moraxella catarrhalis**<br>*Neisseria gonorrhoea* including penicillinase and non-penicillinase producing strains* |
| <u>Gram-Positive Anaerobes:</u><br>*Peptostreptococcus spp.*<br>*Propionibacterium spp.* |
| <u>Spirochetes:</u><br>*Borrelia burgdorferi** |
| Organisms for which acquired resistance may be a problem |

| |
|---|
| Gram-Positive Aerobes:<br>*Streptococcus pneumoniae** |
| Gram-Negative Aerobes:<br>*Citrobacter spp. not including C. freundii*<br>*Enterobacter spp. not including E. aerogenes and E.*<br>*cloacae Escherichia coli**<br>*Klebsiella spp. including Klebsiella*<br>*pneumoniae* Proteus mirabilis*<br>*Proteus spp. not including P. penneri and P.*<br>*vulgaris Providencia spp.* |
| Gram-Positive Anaerobes:<br>*Clostridium spp. not including C. difficile* |
| Gram-Negative Anaerobes: *Bacteroides*<br>*spp. not including B. fragilis*<br>*Fusobacterium spp.* |
| Inherently resistant organisms |
| Gram-Positive Aerobes:<br>*Enterococcus spp. including E. faecalis and E. faecium* |

| |
|---|
| *Listeria monocytogenes* |
| Gram-Negative Aerobes:<br>*Acinetobacter spp. Burkholderia*<br>*cepacia Campylobacter spp.*<br>*Citrobacter freundii Enterobacter*<br>*aerogenes Enterobacter cloacae*<br>*Morganella morganii Proteus*<br>*penneri Proteus vulgaris*<br>*Pseudomonas spp. including Pseudomonas*<br>*aeruginosa Serratia spp.*<br>*Stenotrophomonas maltophilia* |
| Gram-Positive Anaerobes:<br>*Clostridium difficile* |
| Gram-Negative Anaerobes*:*<br>*Bacteroides fragilis* |
| Others:<br>*Chlamydia species*<br>*Mycoplasma species*<br>*Legionella species* |

**Pharmacokinetics**

**Absorption**

After oral administration, cefuroxime axetil is slowly absorbed from the gastrointestinal tract and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa and blood to release cefuroxime into the circulation.

Optimum absorption occurs when it is administered shortly after food or a meal (absolute bioavailability increases from 37% to 52%). Following administration of cefuroxime axetil tablets peak serum levels (2.1mg/l for a 125mg dose, 4.1mg/l for a 250mg dose, 7.0mg/l for a 500mg dose and 13.6mg/l for a 1g dose) occur approximately 2 to 3 hours after dosing when taken with food.

**Distribution**

Protein binding has been variously stated as 33 to 50% depending on the methodology used. Cefuroxime is subsequently distributed throughout the extracellular fluids.

**Metabolism**

Approximately 50% of serum cefuroxime is bound to protein. The axetil moiety is metabolized to acetaldehyde and acetic acid. Cefuroxime is eliminated without any metabolism into the urine.

Serum pharmacokinetic parameters for Cefuroxime tablets are shown in Table 1.

Table 1: Postprandial Pharmacokinetics of Cefuroxime administered as tablets to Adults*

| Dose† (Cefuroxime Equivalent) | Peak Plasma Concentration (mcg/mL) | Time of Peak Plasma Concentration (hr) | Mean Elimination Half- Life (hr) | AUC (mcg-hr mL) |
|---|---|---|---|---|
| 125 mg | 2.1 | 2.2 | 1.2 | 6.7 |
| 250 mg | 4.1 | 2.5 | 1.2 | 12.9 |
| 500 mg | 7.0 | 3.0 | 1.2 | 27.4 |
| 1,000 mg | 13.6 | 2.5 | 1.3 | 50.0 |

*Mean values of 12 healthy adult volunteers.

†Drug administered immediately after a meal

**Elimination**

The serum half life is between 1 and 1.5 hours.

Cefuroxime is excreted by glomerular filtration and tubular secretion. Concurrent administration of probenecid increases the area under the mean serum concentrations time curve by 50%.

**Renal impairment**

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 the urine of pediatric patients has not been studied at this time. Until further data are available, the renal pharmacokinetic properties of cefuroxime axetil established in adults should not be extrapolated to pediatric patients.

Cefuroxime pharmacokinetics has been investigated in patients with various degrees of renal impairment. Cefuroxime elimination half-life increases with decrease in renal function which serves as the basis for dosage adjustment recommendations in this group of patients (See Dosage and Administration). In patients undergoing haemodialysis, at least 60% of the total amount of cefuroxime present in the body at the start of dialysis will be removed during a 4-hour dialysis period. Therefore, an additional single dose of cefuroxime should be administered following the completion of haemodialysis.

As cefuroxime is renally eliminated, the half-life is prolonged in patients with decreased renal function. With reduced renal function. In a study of 20 elderly patients (mean age = 83.9 years) having a mean creatinine clearance of 34.9 mL/min, the mean serum elimination half-life was 3.5 hours. Despite the lower elimination of cefuroxime in geriatric patients, dosage adjustment based on age is not necessary.

**Pre-clinical Safety Data**

Animal toxicity studies indicated that cefuroxime axetil is of low toxicity with no significant findings.

**INDICATIONS**

Cefuroxime Axetil is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to β (beta) -lactamases and is active against a wide range of Gram-positive and Gram-negative organisms. It is indicated for the treatment of infections caused by susceptible bacteria.

Cefuroxime tablets are indicated for the treatment of patients with mild-to-moderate infections caused by susceptible strains of the designated microorganisms.

Susceptibility to cefuroxime axetil will vary with geography and time and local susceptibility data should be consulted where available (See Pharmacological properties, Pharmacodynamics).

**Indications include:**

- Upper respiratory tract infections for example, ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis
- Lower respiratory tract infections for example, pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis
- Genito-urinary tract infections for example, pyelonephritis, cystitis and urethritis
- Skin and soft tissue infections for example, furunculosis, pyoderma and impetigo
- Gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis.
- Treatment of early Lyme disease and subsequent prevention of late Lyme disease in adults and children over 12 years old. Cefuroxime is also available as the sodium salt 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 is effective when used following initial parenteral cefuroxime sodium in the treatment of pneumonia and acute exacerbations of chronic bronchitis.

**DOSAGE AND ADMINISTRATION**

The usual course of therapy is seven days (range 5 to 10 days).

Cefuroxime axetil should be taken after food for optimum absorption.

**Adults**

| | |
|---|---|
| Most infections | 250mg twice daily |
| Urinary tract infections | 125mg twice daily |
| Mild to moderate lower respiratory tract infections e.g. bronchitis | 250mg twice daily |
| More severe lower respiratory tract infections, or if pneumonia is suspected | 500mg twice daily |
| Pyelonephritis | 250mg twice daily |
| Uncomplicated gonorrhea | single dose of 1g |
| Lyme disease in adults and children over the age of 12 years | 500mg twice daily for 20 days |

**Sequential therapy**

**Pneumonia**

1.5g Cefuroxime sodium three times a day or twice a day (intravenous (i.v.) or intramuscular (i.m.)) for 48 to 72 hours followed by cefuroxime axetil oral therapy 500mg twice a day for 7 to10 days.

**Acute exacerbations of chronic bronchitis**

750 mg Cefuroxime sodium three times a day or twice a day (i.v. or i.m.) for 48 to 72 hours followed by cefuroxime axetil oral therapy 500mg twice a day for 5 to 10 days

Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.

**Children**

| | |
|---|---|
| Most infections | 125mg (1 x 125mg tablet) twice daily, to a maximum of 250mg daily. |
| Children aged two years or older with otitis media or, where appropriate, with more severe infections | 250mg (1 x 250mg tablet or 2 x 125mg tablets) twice daily, to a maximum of 500mg daily. |

Cefuroxime axetil tablets should not be crushed and are therefore unsuitable for treatment of patients, such as youngerchildren, who cannot swallow tablets. In children Cefuroxime axetil oral suspension may be used.

There is no experience of using cefuroxime axetil in children under the age of 3 months.

**Renal impairment**

Cefuroxime is primarily excreted by the kidneys. In patients with markedly impaired renal function it is recommended that the dosage of cefuroxime be reduced to compensate for its slower excretion (see the table below).

| Creatinine Clearance | $T_{1/2}$ (hours) | Recommended Dosage |
|---|---|---|
| • Pl/min | 1.4 - 2.4 | No dose adjustment necessary standard dose of 125 mg to 500 mg given twice daily |
| 10-29 ml/min | 4.6 | Standard individual dose given every 24 hours |
| <10 ml/min | 16.8 | Standard individual dose given every 48 hours |
| During haemodialysis | 2 – 4 | A single additional standard individual dose should be given at the end of each dialysis |

**CONTRAINDICATIONS**

Cefuroxime products are contraindicated in patients with a known hypersensitivity to the cephalosporin group of antibiotics.

**WARNINGS & PRECAUTIONS**

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactams. As with other antibiotics, use of cefuroxime axetil may result in the overgrowth of Candida. Prolonged use may also result in the overgrowth of other non-susceptible organisms (e.g. enterococci and Clostridium difficile), which may require interruption of treatment.

Pseudomembranous colitis has been reported with the use of antibiotics, and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

The Jarisch-Herxheimer reaction has been seen following cefuroxime axetil treatment of Lyme disease. It results directly from the bactericidal activity of cefuroxime axetil on the causative organism of Lyme disease, the spirochaete *Borrelia burgdorferi*. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease. 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. If there is no clinical improvement within 72 hours, then the parenteral course of treatment must be continued.

Please refer to the relevant prescribing information for cefuroxime sodium before initiating sequential therapy.

**Ability to perform tasks that require judgment, motor or cognitive skills**

As this medicine may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

**DRUG INTERACTIONS**

Drugs which reduce gastric acidity may result in a lower bioavailability of cefuroxime axetil compared with that of the fasting state and tends to cancel the effect of enhanced post-prandial absorption.

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.

**PREGNANCY AND LACTATION**

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 the early months of pregnancy. 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 frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data (for example from placebo-controlled studies) for calculating incidence were not available. In addition the incidence of adverse reactions associated with cefuroxime axetil may vary according to the indication.

Data from large clinical studies were used to determine the frequency of very common to rare undesirable effects. The frequencies assigned to all other undesirable effects (i.e. those occurring at <1/10,000) were mainly determined using post-marketing data and refer to a reporting rate rather than true frequency. Placebo-controlled trial data were not available. Where incidences have been calculated from clinical trial data, these were based on drug-related (investigator assessed) data.

**The following convention has been used for the classification of frequency:**

Very common ≥ 1/10
Common ≥ 1/100 to <1/10
Uncommon ≥ 1/1000 to <1/100
Rare ≥ 1/10,000 to <1/1000
Very rare <1/10,000

**Infections and infestations**

Common: Overgrowth of Candida

**Blood and lymphatic system disorders**

Common: *Eosinophilia
Uncommon: *Positive Coombs' test, *thrombocytopenia, *leukopenia (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 *(See Warnings and Precautions)*

**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)

**See also Immune system disorders.**

**OVERDOSAGE**

**Signs and symptoms**

Over dosage of cephalosporins can cause cerebral irritation leading to convulsions.

**Treatment**

Serum levels of cefuroxime can be reduced by haemodialysis and peritoneal dialysis.

**STORAGE CONDITION**

Cefuroxime axetil tablets should be stored temperatures not exceeding 30$^{O}$C. Protect from light. Keep all medicines out of reach of children.

**PRESENTATION-** Cefuroxime Axetil 250mg/500mg tablets

**PACKING-** 1*10 TAB

BiosLab® inspired by life

**BIOS LAB PVT. LTD.**
Gujarat-India
www.bioslab.co.in