For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

CEFTUM TABLETS

1. GENERIC NAME

Cefuroxime Axetil Tablets IP 250/500 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CEFTUM TABLETS 250

Each film-coated tablet contains:
Cefuroxime Axetil IP equivalent to Cefuroxime 250 mg
Excipients ……..q.s.
Colour: Titanium Dioxide IP

CEFTUM TABLETS 500

Each film-coated tablet contains:
Cefuroxime Axetil IP equivalent to Cefuroxime 500 mg
Excipients ……..q.s.
Colour: Titanium Dioxide IP

List of Excipients

Citric Acid Anhydrous, Sodium Hydrogen Carbonate, Crospovidone, Croscarmellose Sodium, Sodium Lauryl Sulfate, Silica Colloidal anhydrous, Cellulose Microcrystalline (Avical PH 112), Talc, Opadry 3H580000 White, Purified Water* (*evaporates during processing).

3. DOSAGE FORM AND STRENGTH

Film-coated tablets

For information on strengths refer *2. Qualitative and Quantitative Composition* above.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication

Cefuroxime axetil is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to most 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. Susceptibility to cefuroxime axetil will vary with geography and time, and it should be used in accordance with local official antibiotic prescribing guidelines and local susceptibility data (See *5.2 Pharmacodynamic Properties*).

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 exacerbations of chronic obstructive pulmonary disease)

- 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

Cefuroxime is also available as the sodium salt (*SUPACEF*) 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 *CEFTUM* (cefuroxime axetil) is effective when used following initial parenteral *SUPACEF* (cefuroxime sodium) in the treatment of pneumonia and acute exacerbations of chronic obstructive pulmonary disease.

4.2 Posology and Method of Administration

The usual course of therapy is seven days (range five to ten days). The dose of cefuroxime that is selected to treat an individual infection should take into account:

- the expected pathogens and their likely susceptibility to cefuroxime axetil
- the severity and the site of the infection
- the age, weight and renal function of the patient; as shown below

The duration of therapy should be determined by the type of infection and the response of the patient and should generally not be longer than recommended.

CEFTUM tablets should be taken after food for optimum absorption.

Adults and Children weighing more than 40 kg

Indication	**Dosage**
Acute tonsillitis and pharyngitis	250 mg twice daily
Acute otitis media	500 mg twice daily
Acute bacterial sinusitis	500 mg twice daily
Community acquired pneumonia	
Acute exacerbations of chronic obstructive pulmonary disease	
Urinary tract infections	250 mg - 500 mg twice daily
Uncomplicated gonorrhoea	single dose of 1,000 mg
Skin and soft tissue infections	250 mg - 500 mg twice daily

Sequential therapy

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

Pneumonia

1,500 mg *SUPACEF* (cefuroxime sodium) three times a day or twice a day (intravenous [i.v.] or intramuscular [i.m.]) for 48 to 72 hours, followed by 500 mg twice a day *CEFTUM* oral therapy for 7 to 10 days.

Acute exacerbations of chronic obstructive pulmonary disease

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

Children weighing between 20-40 kg

CEFTUM tablets should not be crushed or split and are therefore unsuitable for treatment of patients, such as younger children, who cannot swallow whole tablets.

Indication	**Dosage**
Acute tonsillitis and pharyngitis	250 mg twice daily
Acute otitis media	250 mg twice daily to 500 mg twice daily
Acute bacterial sinusitis	
Community acquired pneumonia	
Urinary tract infections	
Skin and soft tissue infections	

Special patient populations

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**
≥30 ml/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

Hepatic impairment

There are no data available for patients with hepatic impairment. Since cefuroxime is primarily eliminated by the kidneys, the presence of hepatic dysfunction is expected to have no effect on the pharmacokinetics of cefuroxime.

4.3 Contraindications

Patients with known hypersensitivity to cephalosporin antibiotics.

4.4. Special Warnings and Precautions for Use

Hypersensitivity reactions

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactam antibiotics because there is a risk of cross-sensitivity. As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported.

There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction, see *section 4.8 Undesirable Effects*). In case of severe hypersensitivity reactions, treatment with cefuroxime must be discontinued immediately and adequate emergency measures must be initiated.

Overgrowth of non-susceptible microorganisms

As with other antibiotics, use of *CEFTUM* may result in the overgrowth of *Candida* (see section *4.8 Undesirable Effects*). 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.

Sequential therapy

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.

4.5 Drug Interactions

Medicinal products which reduce gastric acidity may result in a lower bioavailability of *CEFTUM* compared with that of the fasting state and tend to cancel the effect of enhanced post-prandial absorption.

In common with other antibiotics, *CEFTUM* 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 *CEFTUM*. This antibiotic does not interfere in the alkaline picrate assay for creatinine.

4.6 Use in Special Populations

Pregnancy

There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime axetil but, as with all medicinal products, it should be administered with caution during the early months of pregnancy.

Lactation

Cefuroxime is excreted in human milk in small quantities. Adverse effects at therapeutic doses are not expected, although a risk of diarrhoea and fungal infection of the mucous membranes cannot be excluded. Breastfeeding might have to be discontinued due to these effects. The possibility of sensitisation should be taken into account. Cefuroxime should only be used during breastfeeding after benefit/risk assessment by the physician.

4.7 Effects on Ability to Drive and Use Machines

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

4.8 Undesirable 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
not known (cannot be estimated from the available data)

Infections and infestations	
Common:	Candida overgrowth (see section *4.4 Special Warnings and Precautions for Use*)
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.	
Cardiac disorders	
Very rare:	Kounis syndrome (*see section 4.4 Special Warnings and Precautions for Use)*
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 *4.4 Special Warnings and Precautions for Use*)
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)
Not known:	Angioneurotic oedema
See also Immune system disorders.	

Paediatric Population:

The safety profile for cefuroxime axetil in children is consistent with the profile in adults.

4.9 Overdose

Signs and Symptoms

Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment *(see section 4.2 Posology and Method of Administration and section 5.3 Pharmacokinetic Properties)*.

Treatment

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

5. PHARMACOLOGICAL PROPERTIES

ATC code

Pharmacotherapeutic group: antibacterials for systemic use, second-generation cephalosporins

ATC-Code: J01DC02

5.1 Mechanism of Action

Cefuroxime axetil owes its *in vivo* bactericidal activity to the parent compound cefuroxime.

Cefuroxime is a well characterised and effective antibacterial agent which has bactericidal activity against a wide range of common pathogens, including beta-lactamase producing strains.

Cefuroxime has good stability to bacterial beta-lactamase, and consequently is active against many ampicillin-resistant or amoxycillin-resistant strains. The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

5.2 Pharmacodynamic Properties

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** Where clinical efficacy of cefuroxime axetil has been demonstrated in clinical trials this is indicated with an asterisk (*).
Commonly Susceptible Species
Gram-Positive Aerobes: *Staphylococcus aureus* (methicillin susceptible)* *Coagulase negative staphylococcus* (methicillin susceptible) *Streptococcus pyogenes** Beta-hemolytic streptococci
Gram-Negative Aerobes: *Haemophilus influenzae** including ampicillin resistant strains *Haemophilus parainfluenzae** *Moraxella catarrhalis** *Neisseria gonorrhoea** including penicillinase and non-penicillinase producing strains
Gram-Positive Anaerobes: *Peptostreptococcus* spp. *Propionibacterium* spp.
Spirochetes: *Borrelia burgdorferi**
Organisms for which acquired resistance may be a problem
Gram-Positive Aerobes: *Streptococcus pneumoniae**
Gram-Negative Aerobes: *Citrobacter* spp. not including *C. freundii* *Enterobacter* spp. not including *E. aerogenes* and *E. cloacae* *Escherichia coli** *Klebsiella* spp. including *Klebsiella pneumoniae** *Proteus mirabilis* *Proteus* spp. not including *P. penneri* and *P. vul*garis *Providencia* spp.
Gram-Positive Anaerobes: *Clostridium* spp.
Gram-Negative Anaerobes: *Bacteroides* spp. not including *B. fragilis* *Fusobacterium* spp.
Inherently resistant organisms
Gram-Positive Aerobes: E*nterococcus* spp. including *E. faecalis* and *E. faecium* *Listeria* monocytogenes
Gram-Negative Aerobes: *Acinetobacter* spp.

Burkholderia cepacia *Campylobacter* spp. *Citrobacter freundii* *Enterobacter aerogenes* *Enterobacter cloacae* *Morganella morganii* *Proteus penneri* *Proteus vulgaris* *Pseudomonas* spp. including *Pseudomonas aeruginosa* *Serratia* spp. *Stenotrophomonas maltophilia*
Gram-Positive Anaerobes: *Clostridioides difficile*
Gram-Negative Anaerobes: *Bacteroides fragilis*
Others: *Chlamydia* species *Mycoplasma* species *Legionella* species

5.3 Pharmacokinetic Properties

Absorption

After oral administration cefuroxime axetil is slowly absorbed from the gastrointestinal tract and rapidly hydrolysed in the intestinal mucosa and blood to release cefuroxime into the circulation.

Optimum absorption occurs when it is administered shortly after a meal.

Following administration of cefuroxime axetil tablets peak serum levels (2.1 mg/l for a 125 mg dose, 4.1 mg/l for a 250 mg dose, 7.0 mg/l for a 500 mg dose and 13.6 mg/l for a 1 g 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.

Metabolism

Cefuroxime is not metabolised.

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%.

Special Patient Populations

Renal impairment

Cefuroxime pharmacokinetics have 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 *4.2 Posology and Method of 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.

Hepatic impairment

There are no data available for patients with hepatic impairment. Since cefuroxime is primarily eliminated by the kidneys, the presence of hepatic dysfunction is expected to have no effect on the pharmacokinetics of cefuroxime.

Paediatric population

In older infants (aged >3 months) and in children, the pharmacokinetics of cefuroxime are similar to that observed in adults.
There are no clinical trial data available on the use of cefuroxime in children under the age of 3 months.

6. NONCLINICAL PROPERTIES

6.1 Animal Toxicology and Pharmacology

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

7. DESCRIPTION

Film-coated tablets

CEFTUM TABLETS 250

Each film-coated tablet contains:
Cefuroxime Axetil IP equivalent to Cefuroxime 250 mg
Excipients ……..q.s.
Colour: Titanium Dioxide IP

CEFTUM TABLETS 500

Each film-coated tablet contains:
Cefuroxime Axetil IP equivalent to Cefuroxime 500 mg
Excipients ……..q.s.
Colour: Titanium Dioxide IP

List of Excipients

Citric Acid Anhydrous, Sodium Hydrogen Carbonate, Crospovidone, Croscarmellose Sodium, Sodium Lauryl Sulfate, Silica Colloidal anhydrous, Cellulose Microcrystalline (Avical PH 112), Talc, Opadry 3H580000 White, Purified Water* (*evaporates during processing).

8. PHARMACEUTICAL PARTICULARS

8.1 Incompatibilities

In the absence of compatibility studies cefuroxime axetil must not be mixed with other medicinal products.

8.2 Shelf Life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Alu-Alu Blisters packed in a carton.

8.4 Storage and Handling Instructions

Keep out of reach of Children
Store protected from moisture, at a temperature not exceeding 30°C.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or patients' caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contraindications of *CEFTUM*. Patients (and/or patients' caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

The Manufacturing Site details are mentioned on the label and packaging.
For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office:
Dr. Annie Besant Road, Worli
Mumbai 400 030, India.

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging.

12. DATE OF REVISION

24-JUL-2026

Trade marks are owned by or licensed to the GSK group of companies.

Version: CEF-CL/PI/IN/2026/01

Adapted from Cefuroxime axetil PDS v03 dated 09 July 2025.