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Pharmacode Direction

30 mm

XXXXX
Cetil 500 (Malaysia)

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

CETIL 500 mg Tablet

(Cefuroxime Axetil Tablets USP)

Description
White to off white coloured biconvex, film coated tablets with breakline on one side and "LUPIN" inscription on other side.

Dosage form : Film Coated Tablets
Composition
Each film-coated tablet contains:
Cefuroxime 500 mg
(As Cefuroxime Axetil amorphous USP)

Clinical Pharmacology
Cefuroxime Axetil is the acetyloxyethyl ester of Cefuroxime. Cefuroxime Axetil belongs to the second generation of Cephalosporins and compared to the first generation of Cephalosporin are not only active against gram positive but also against gram negative organisms. The mechanism of action of Cefuroxime Axetil is similar to all the Cephalosporins and it acts by combining with the penicillin bound proteins (PBP) part of bacterial cell wall resulting in the lysis of the cell wall and as a consequence causing cell death and therefore having a bactericidal action. Cefuroxime Axetil is the prodrug of the active compound Cefuroxime. When given orally, Cefuroxime Axetil is hydrolysed to Cefuroxime by non specific esterases in the intestinal mucosa. Cefuroxime is subsequently distributed throughout the extracellular fluid. The Axetil part is metabolised to acetaldehyde and acetic acid.

Antibacterial activity
Aerobic gram positive micro-organisms:
Staphylococcus aureus (including B-lactamase producing strains but not methicillin resistant strains,), Streptococcus pneumoniae, Streptococcus pyogenes.

Aerobic gram negative micro-organisms:
Escherichia coli, Haemophilus influenza (including B-lactamase producing strain), Haemophilus parainfluenza, Klebseilla peneumoniae, Moraxella catarrhalis, Neisseria
gonorrhea (beta lactamase negative strains only)

In-vitro activity is present against the following organisms:
Staphylococcus epidermidis, Moraganella morganii, Neisseria gonorrhea (beta-lactamase-producing strains only), Proteus mirabilis.

Pharmacokinetics
Following oral administration, 30-50% of the drug is absorbed. Around 50% of serum Cefuroxime is protein bound. The peak plasma concentration (C^{max}) following oral administration of 125 mg, 250 mg & 500 mg of Cefuroxime Axetil in normal heallhy adults is reported to be 2.1, 4.1 & 7.0/µg/ml &the time for peak plasma concentration (T^{max}) ranges from 2-3 hours. The mean elimination half life (T^{max}) is approximately 1.2 hours of all the 3 doses.
Cefuroxime is eliminated unchanged in the urine, and 50% of the administered dose is recovered in the urine in 12 hours. The serum half life is therefore prolonged in patients with reduced renal function. However no special precaution are necessary in patients with renal impairment or on renal dialysis or in the elderly at doses up to normal maximum of 1 g/day.

Indication
Cefuroxime axetil is indicated for the treatment of the following infections caused by sensitive bacteria:
Lower respiratory tract infection e.g. acute bronchitis, acute exacerbations of chronic bronchitis and pneumonia.
Upper respiratory tract infections e.g. ear, nose, throat infections such as otitis media, sinusitis, tonsilitis and pharyngitis.
Uncomplicated Genitourinary tract infections e.g. pyelonephritis, cystitis and urethritis.
Uncomplicated Skin & soft tissue infections e.g. furunculosis, pyoderma and impetigo.
Gonorrhea e.g. acute uncomplicated gonococcal urethritis and cervicitis.

Route of administration: Oral
Dosage
The usual course of therapy is 7 days (Range 5 10 days)
It should be taken after food for optimum absorption

Adults:
Most infections 250mg bd
Urinary tract infections 125mg bd
Mild to moderate lower tract infection e.g. bronchitis 250mg bd
More severe lower tract infections, or if pneumonia is suspected 500mg bd
Pyelonephritis 250mg bd
In uncomplicated gonorrhea a single dose of 1g.

Children:
Most infections - 125mg bd, to a maximum of 250mg daily
Children aged two years or older with otitis media or where appropriate, with more severe infections 250mg bd, to a maximum of 500mg daily.

Contraindication
Cetil is contraindicated if there is a history of hypersensitivity to Cephalosporins, or with Cefuroxime itself.

Interaction with other Medicaments:
Cefuroxime Axetil is not bioequivalent and is therefore not substitutable on a mg/mg basis.
Before therapy with Cefuorxime Axetil is instituted, careful inquiry should be made to determine whether the patient has had

RABRO ADVERTISING & MARKETING

Market/Customer :-	Malaysia	**Location**	Mandideep
Prepared On	23/08/2025	**Tracking No.**	0
Product name	Cetil 500 mg Tablet		
Material code	XXXXX	**Supercedes Material code**	267196
Open Size	180 x 225 mm (W x H) ± 3 mm	**Pharmacode value**	XXXX
Folded Size	180 x 30 mm (W x H) ± 3 mm	**Component**	Leaflet
GSM :	54 ± 10% gsm Creamwove Paper		
Pantone Colours	Black		
Reason of Revision:	Text added in Warning & Precautions, Date of revision updated, Marketing Authorization Holder updated to Product Registration Holder		

Rabro Advertising & Marketing
Artwork Same Size:
Size: 180 x 225 mm (W x H)
Comp1:D/Jobs/Lupin-Ltd/ROW/Registration/Packinsert/Cetil- 500 mg Tablet (Malaysia) Aug-2025 PI XXXXX
1st Laser Proof 23/08/2k25

previous hypersensitivity reactions to cefuroxime axetil, other cephalosporins, penicillins, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in upto 10% of patients with a history of penicillin allergy. If a clinically significant allergic reaction to Cefuroxime Axetil occurs, discontinue the drug and institute appropriate therapy, serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous anti-histamines, corticosteroids, pressor amines, and airway management, as clinically indicated.

Pseudomembranous colitis has been reported with nearly all-antibacterial agents, including Cefuroxime, and may range from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

After diagnosis of pseudomembranous colitis has been established, appropriate therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug effective against *Clostridium difficile*.

Pregnancy and Lactation:
Pregnancy Category B. Reproduction studies have been performed in rats and mice at doses upto 3200 mg/kg per day (23 times the recommended maximum human dose based on mg/m^2) and have revealed no evidence of harm to the fetus due to Cefuroxime Axetil. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Because Cefuroxime is excreted in human milk, consideration should be given to discontinuing nursing temporarily during treatment with Cefuroxime Axetil.

Warnings and Precaution
Cetil may be given safely to patients who are hypersensitive to penicillins. Special care is indicated in patients who have experienced anaphylectoid reactions with penicillin. Prolonged use of Cefuroxime may result in overgrowth of non susceptible organism. There is no evidence of embryogenic & teratogenic effects due to Cefuroxime Axetil. Should be administered with caution in pregnancy especially during the early period. Cefuroxime is excreted in milk.Jarisch Herxheimer reactions has been reported following administration of cefuroxime in Lyme's disease. Pseudomembranous colitis has been reported with Cefuroxime. A false positive reaction for glucose in the urine may occur with copper reductive tests (Benedicts test) .It is recommended that either the glucose oxidase or hexokinase methods be used to determines blood/plasma glucose level. Should be given with caution to patients receiving concurrent treatment with potent diuretics.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reaction) have been reported in patients receiving therapy with beta-lactaams. Before initiating therapy with [Cetil 500 mg], careful inquiry should be made concerning previous hypersensitivity reaction to penicillins, cephalosporins, carbapenems or other beta-lactam agents. if an allergic reaction occurs, [Cetil 500 mg] must be discontinued immediately and appropriate alternative therapy institute.

Side Effects
They are usually mild &transient in nature. GI disturbances including diarrhoea & nausea & vomiting & headache have been reported. Eosinophilia.& transient increase of hepatic enzymes (SGPT, OT & LIH) have also been reported. Jaundice & Steven Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, serum sickness like reactions, anaphylaxis and angioedema have been reported rarely.

Overdosage
Can cause cerebral irritation leading to convulsions. Serum levels can be reduced by haemodialysis & peritoneal dialysis.

Presentation
Available as a blister strip of 10 tablets. 1 such strips are packed in a carton along with pack insert.

Storage
Store in dry place at the temperature not exceeding 30°C. Protect from light.

Shelf Life: 24 months

Date of Revision: 12/08/2025

For further information please write to :

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