SUMMARY OF PRODUCT CHARACTERISTICS

EXATIL-500 (CEFUROXIME AXETIL TABLETS USP 500 MG)

1. NAME OF THE MEDICINAL PRODUCT:

EXATIL - 500
CEFUROXIME AXETIL TABLETS USP 500 MG

COMPOSITION:
Each film coated tablet contains:
Cefuroxime Axetil U.S.P
Eq. to Cefuroxime 500 mg
Excipients q.s
Colour: Titanium Dioxide

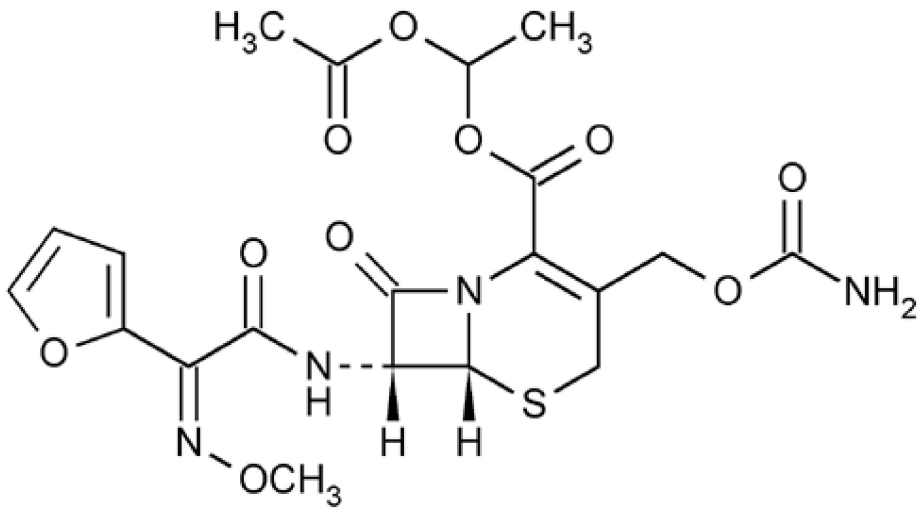
2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

CHEMICAL NAME AND THE STRUCTURAL FORMULA OF EACH ACTIVE INGREDIENT:-

CEFUROXIME AXETIL

Chemical Name:
1-acetyloxyethyl (6*R*,7*R*)-3-(carbamoyloxymethyl)-7-[[(2*Z*)-2-(furan-2-yl)-2-methoxyiminoacetyl] amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate

Chemical Structure:



Molecular Formula: $C_{20}H_{22}N_4O_{10}S$

Molecular Weight: 510.48 g/mol

NAME AND QUANTITY OF EACH INGREDIENT:

UNIT DOSE

Ingredients	Qty./ Tab In mg	Use/Function
Active Ingredient		
Cefuroxime Axetil U.S.P eq.to Cefuroxime	600.00 500.00	Antibacterial Agent
In Active Ingredients		
Base Granules Speci. (Lactose:MCC i.e. 7:3)	439.35	Diluent
Sodium Lauryl sulfate BP	12.80	Surfactant
Magnesium Stearate BP	12.80	Lubricant
Talcum BP	19.80	Glidant
Aerosil BP	12.80	Glidant
Sodium Starch Glycolate BP	152.45	Disintegrant
FC Titanium Dioxide BP	30.00	Colouring agent
Iso Propyl Alcohol BP	---	Solvent
Methylene chloride BP	---	Solvent

Reference:
USP= United States Pharmacopeia
BP = British Pharmacopoeia
IHS= In- House Specification

3. PHARMACEUTICAL FORMS:
Film-coated tablets
White to Off white coloured, oblong shaped film coated tablets

CLINICAL PARTICULARS:

4. INDICATIONS FOR USE:
EXATIL-500 is indicated for the treatment of infections caused by susceptible strains of the following organisms in the following infections:

- Pharyngitis and tonsillitis caused by *Streptococcus pyogenes.*
- Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (ampicillin-sensitive and resistant strains), *Moraxella (Branhamella) catarrhalis* and *Streptococcus pyogenes.*
- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae.*
- Acute and chronic bronchitis caused by *Streptococcus pneumoniae, Haemophilus influenzae*(ampicillin-sensitive strains) and *Haemophilus parainfluenzae* (ampicillin-sensitive strains).

- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae.*
- Lyme disease caused by *Borrelia burgdorferi.*

5. CONTRAINDICATIONS:
Hypersensitivity to cephalosporin antibiotics or to any components of the formulation. Hypersensitivity to penicillin and other beta-lactam antibiotics.

6. WARNING AND PRECAUTIONS :
EXATIL-500 should be used with caution in patients with;
History of gastrointestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.

Renal function impairment - A reduced dose may be required.

PREGNANCY:
Pregnancy Category B. Reproduction studies have been performed in mice at doses up to 3,200 mg/kg/day (14 times the recommended maximum human dose based on mg/m2) and in rats at doses up to 1,000 mg/kg/day (9 times the recommended maximum human dose based on mg/m2) and have revealed no evidence of impaired fertility or 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.

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

7. SIDE EFFECTS:
Hypersensitivity reactions including skin rashes, urticaria, pruritus, bronchospasm, drug fever, serum sickness, anaphylaxis.

8. DRUG INTERACTIONS:
Oral Contraceptives
Cefuroxime axetil may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives. Counsel patients to consider alternate supplementary (non-hormonal) contraceptive measures during treatment.

Drugs That Reduce Gastric Acidity
Drugs that reduce gastric acidity may result in a lower bioavailability of Cefuroxime axetil compared with administration in the fasting state.

Probenecid
Concomitant administration of probenecid with cefuroxime axetil tablets increases serum concentrations of cefuroxime
Coadministration of probenecid with cefuroxime axetil is not recommended.

9. DOSAGES AND ADMINISTRATION:

Adults and children over 12 years of age: 500 mg twice daily for 20 days.

EXATIL-500 should be taken half an hour after food for optimum absorption.

OR

As directed by physician.

Method of Administration
For oral administration

10. OVERDOSAGE:
Seizures have been reported.
Treatment is symptomatic and supportive. Serum levels of EXATIL-500 can be reduced by hemodialysis or peritoneal dialysis.

11. PHARMACOLOGY:
Cefuroxime is a β-lactam type antibiotic. More specifically, it is a second-generation cephalosporin. Cephalosporins work the same way as penicillins: they interfere with the peptidoglycan synthesis of the bacterial wall by inhibiting the final transpeptidation needed for the cross-links. This effect is bactericidal. Cefuroxime is effective against the following organisms: Aerobic Gram-positive Microorganisms: *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*. Aerobic Gram-negative Microorganisms: *Escherichia coli*, *Haemophilus influenzae* (including beta-lactamase-producing strains), *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis* (including beta-lactamase-producing strains), *Neisseria gonorrhoeae* (including beta-lactamase-producing strains). Spirochetes: *Borrelia burgdorferi*. Cefuroxime axetil is the prodrug.

12. PHARMACOKINETICS:

Absorption:
Cefuroxime axetil is an oral prodrug of cefuroxime. After oral absorption, cefuroxime axetil is hydrolysed in the intestinal mucosa and blood to release cefuroxime into the plasma. Oral absorption is optimal when administered with food. Peak serum levels of cefuroxime occur approximately 2 to 3 hours after oral dosing, when taken with food.

Distribution:
Protein binding is approximately 33% to 50%.

Metabolism & Excretion:
Cefuroxime is not metabolised and is excreted unchanged in the urine by glomerular filtration and tubular secretion. The elimination half-life is between 1 and 1,5 hours after oral dosing. The elimination half-life is prolonged with renal impairment. Serum levels of cefuroxime are reduced by dialysis.

13. STORAGE:
Do not store above 25°C. Store in an airtight container, protected from light.
Do not remove blisters from carton until required for use.
KEEP OUT OF THE REACH OF CHILDREN.

14. SHELF-LIFE:
24 MONTHS