SUMMARY OF PRODUCT CHARACTERISTICS

EXATIL (Cefuroxime Axetil for Oral Suspension USP 125 mg / 5 ml)

1. NAME OF THE MEDICINAL PRODUCT:

EXATIL
CEFUROXIME AXETIL FOR ORAL SUSPENSION USP 125 MG / 5 ML for Paediatric use

COMPOSITION:
When constituted as directed
Each 5 ml reconstituted suspension contains:
Cefuroxime Axetil USP
Eg. to Cefuroxime 125 mg
Excepients Q.S.

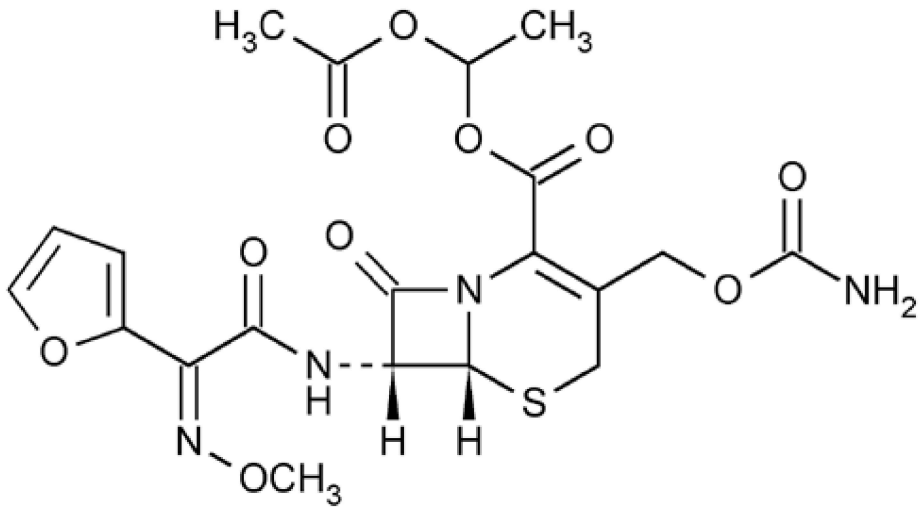
2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS:

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	Unit formula mg /5 ml	Use/Function
Active Ingredient		
Cefuroxime Axetil U.S.P eq.to Cefuroxime	150.00 125.00	Antibacterial Agent
In Active Ingredients		
Aerosil (Cabosil) BP	6.35	Flocculating agents
M.C.C.Powder BP	165.31	Anticaking agent
Menthol BP	2.52	Cooling effect
Sodium Benzoate BP	7.66	Preservative
Sodium Chloride BP	12.63	Adjust drug release
Xanthan Gum BP	0.95	Suspending agent
Acesulfame Potassium	20.43	Sweetener
Colour Erythrosine Supra	0.1	Colour
Ess Strawbarry Dry Powder	11.47	Flavour

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

3. PHARMACEUTICAL FORMS:
Granules for constitution with water to form a suspension for oral administration

CLINICAL PARTICULARS:

4. INDICATIONS FOR USE:
Cefuroxime axetil is an oral prodrug of the bactericidal cephalosporin antibiotic cefuroxime, which is resistant to mostB-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 sensitive bacteria.
Indications include: Lower respiratory tract infections for example, acute bronchitis,acute exacerbations of chronic bronchitis and pneumonia.Upper respiratory tract infections for example, ear, nose, throat infections, such as otitis media, sinusitis, fonsillitis and Genito-urinary tract infections forexample, pyelonephritis, cystitis and urethritis.Skin and pharyngitis.
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.
This permits the use of sequential therapy with the same antibiotic, when a change from parenteral to oral therapy is clinically indicated.

5. CONTRAINDICATIONS:
Hypersensitivity to cephalosporin antibiotics.

6. WARNING AND 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 non-susceptible organisms (e.g. Enterococci and Clostridium difficile), which may require interruption of treatment.
Pseudomembranous colitis has been reported with the use of broad-spectrum antibiotics, therefore, serious diarrhoea during or after antibiotic use.
The Jarisch-Herxheimer reaction has been seen following EXATIL treatment of is important to consider its diagnosis in patients who developLyme disea disease. results from the bactericidal activity of EXATIL on the causative diceos organism of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be orgasm, reassured that this treatment of Lyme disease. a common and usually self-limited consequence of antibiotic 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. The change to oral therapy should only be made once there is a clear clinical
improvement. If there has been no clinical improvement after 72 hours of parenteral treatment, then the patient's treatment should be reviewed. Please refer to the relevant prescribing information for cefuroxime sodium before initiating sequential therapy.

7. SIDE EFFECTS:
Adverse drug reactions to cefuroxime axetil are generally mild and transientin nature.

8. DRUG INTERACTIONS:

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 increases serum concentrations of cefuroxime
Coadministration of probenecid with cefuroxime axetil is not recommended.

9. DOSAGES AND ADMINISTRATION:

Children: The usual dose is 125mg b.d. (5ml of suspension), or 10mg/kg b.d. to a maximum of 250mg daily.

For otitis media, in children less than 2 years of age the usual dosage is 125mg b.d., or 10mg/kg b.d. to a maximum of 250mg daily and in children over 2 years of age, 250mg b.d. , or 15mg/kg b.d. to a maximum of 500mg daily. There is no experience in children under 3 months of age.

Usual course of therapy is seven days.

OR
As directed by physician.

Method of Administration
For oral administration

10. OVERDOSAGE:

Overdosage of cephalosporins can cause cerebral irritancy leading to convulsions.

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

11. PHARMACOLOGY:

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.

Microbiology:

Cefuroxime axetil owes its in vivo bactericidal activity to the parent compound, cefuroxime. Cefuroxime is a well-characterized and effective antibacterial agent which has broad-spectrum 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 and amoxicillin-resistant strains. The bactericidal action of cefuroxime results from inhibition of cell-wall synthesis by binding to essential target proteins.

Cefuroxime is usually active against the following organisms in vitro:

Aerobes, Gram-negative: Haemophilus influenzae (including ampicillin-resistant strains); Haemophilus parainfluenzae; Moraxella catarrhalis; Escherichia coli; Klebsiella species; Proteus mirabilis; Proteus inconstans; Providencia species; Proteus rettgeri and Neisseria gonorrhoea (including penicillinase and non- penicillinase-producing strains).

Aerobes, Gram-positive: Staphylococcus aureus (including penicillinase-producing strains but excluding methicilin-resistant strains): Staphylococcus epidermidis, (including penicillinase producing strains but excluding methicillin-resistant strains);

Streptococcus pyogenes (and betahaemolytic streptococci), Streptococcus pneumoniae; Streptococcus Group B (Streptococcus agalactiae) and Propionibacterium species. Certain strains of enterococci, eg. Streptococcus faecalis, are resistant. Anaerobes, Gram-positive and Gram-negative cocci (including Peptococcus and Peptostreptococcus species); Gram-positive bacilli (including Clostridium species) and Gram-negative bacilli (including Bacteroides and Fusobacterium species). Most strains of Bacteroides fragilis are resistant. organisms, Borrelia burgdorferi. Pseudomonas species, Campylobacter species, Acinetobacter calcoaceticus, Listeria monocytogenes, Legionella species and most strains of Serratia and Proteus vulgaris and Clostridium difficile are resistant to many cephalosporins including cefuroxime.

12. PHARMACOKINETICS:

After oral administration, cefuroxime axetil is 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 after a meal. Peakserum cefuroxime levels occurapproximately two to three hours after oral dosing.

The serum half life is about 1.2 hours. Approximately 50% of serum cefuroxime is protein bound. Cefuroxime is not metabolised and is excreted by glomerular filtration and tubular secretion. Concurrent administration of probenecid increases the area under the mean serum concentration time curve by 50%. Serum levels of cefuroxime.

13. STORAGE:

Store in a cool, dry place.

Keep out of reach of children.

14. SHELF-LIFE:

24 MONTHS