CEFUROXIME POWDER FOR ORAL SUSPENISON

ROENTGEN IMPEX

Module 1: - Administrative information and prescribing information:

1.3.1 Summary of Product Characteristics (SmPC):

Summary Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

CEFUROXIME POWDER FOR ORAL SUSPENSION

Composition
Each 5ml of reconstituted suspension contains
Cefuroxime Axetil USP
eq. to Cefuroxime 125mg
Excipients q.s.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Batch Size: 7270 Bottles

Ingredients	Qty./ mg / 5 ml	Use/Function
* Cefuroxime Axetil USP eq. to Cefuroxime	23.742	Active material
Kyroyn T114C (Polacrilin potassium USP)	53.420	Taste masking/stabilizer
Acetone BP	25.445	solvent
Sucrose BP	303.886	Sweetening agent
Sodium Benzoate BP	1.454	Preservative
Sucralose BP	2.472	Sweetening agent
Bitter taste mask flavor str-dm 10139A IHS	1.163	Taste masking agnet
HPC LH-21 BP (Hydroxypropyl cellulose)	1.527	Solubility enhancer
Sodium citrate BP	5.671	For ph adjustment
Citric acid BP	2.763	Stabilization/ ph adjustment
Menthol BP	0.509	Flavouring agent
flavor IHS	3.344	-
DM Water	QS	
Total Material Weight per Bottle : 55.014 gm		

***** Quantity to be changed based on potency of API.
USP = United States Pharmacopeia
BP = British Pharmacopoeia

IHS= In-house Specification

3. PHARMACEUTICAL FORM
Oral Suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
CEFUROXIME POWDER FOR ORAL SUSPENSION 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.

4.2 Posology and method of administration
CEFUROXIME POWDER FOR ORAL SUSPENSION should be taken half an hour after food for optimum absorption.
Dosage:
The following two tables for r simplified administration, e.g measuring spoon (5 mL), for the 125 mg/5 mL or the 250 mg/5mL multi- dose suspension.

10 mg/kg dosage for most infections

Age	**Dose (mg) twice daily**	**Volume per dose (ml)**	
		125mg	**250mg**
3 to 6 Months	40 to 60	2.5	-
6 Months to 2years	60 to 120	2.5 to 5	-
2 to 18 years	125	5	2.5

Method of Administration
Oral use
For optimal absorption cefuroxime axetil suspension should be taken with food.
4.3 Contraindications
Hypersensitivity to cephalosporin antibiotics or to any components of the formulation. Hypersensitivity to penicillin and other beta-lactam antibiotics.

4.4 Special warnings and precautions for use

CEFUROXIME POWDER FOR ORAL SUSPENSION 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.

4.5 Interaction with other medicinal products and other forms of interaction

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 CEFTIN compared with administration in the fasting state. Administration of drugs that reduce gastric acidity may negate the food effect of increased absorption of CEFTIN when administered in the postprandial state. Administer CEFTIN at least 1 hour before or 2 hours after administration of short-acting antacids. Histamine-2 (H2) antagonists and proton pump inhibitors should be avoided.

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

Drug/Laboratory Test Interactions
A false-positive reaction for glucose in the urine may occur with copper reduction tests (e.g., Benedict's or Fehling's solution), but not with enzyme-based tests for glycosuria. As a false-negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase method be used to determine blood/plasma glucose levels in patients receiving cefuroxime axetil. The presence of cefuroxime does not interfere with the assay of serum and urine creatinine by the alkaline picrate method.

4.6 Pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines
Fluconazole has no or negligible influence on the ability to drive and use machines However when driving vehicles or operating machines it should be taken into account that occasionally dizziness or seizures may occur.

4.8 Undesirable effects
- diarrhea
- dizziness
- headache
- drowsiness
- itching/swelling
- rash
- nausea
- vomiting
- abdominal pain
- stomach upset
- gas
- headache
- itching or rash

4.9 Overdose
Seizures have been reported.
Treatment is symptomatic and supportive. Serum levels of EXATIL Dry Syrup can be reduced by hemodialysis or peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamics properties

Pharmacotherapeutic Group
Antimycotics for systemic use, triazole derivatives
ATC code: J02AC01

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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Preclinical data from conventional studies on repeat-dose/general toxicity, genotoxicity or carcinogenicity indicate no special hazard for humans not already considered in other sections of the SPC.

In reproduction toxicity studies in rat an increased incidence of hydronephrosis and extension of renal pelvis was reported and embryonal lethality was increased. An increase in anatomical variations and delayed ossification was noted as well as prolonged delivery and dystocia. In reproduction toxicity studies in rabbits abortions were recorded.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. no.	Name of Excipients	Pharmacopeia
1	Kyroyn T114C (polacrilin potassium USP)	USP
2	Acetone	BP
3	Sucrose BP	BP
4	Sodium Benzoate BP	BP
5	Sucralose BP	BP
6	Bitter taste mask flavor str-dm 10139A	IHS
7	Hydroxypropyl cellulose (HPC LH-21)	BP
8	Sodium citrate	BP
9	Citric acid	BP
10	Menthol	BP
11	flavor	IHS

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C. Protect from light. KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container
Pack size:1 x 100 ml bottle in a mono-Pack.

Sr. no.	Container Closure System
1.	100 ml milkey white bottle round
2.	25 mm Plastic cap with induction seal
3.	Printed Labels
4.	Printed Mono Carton
5.	Printed Inserts
6.	Measuring Cap 15 ml.
7.	Plain BOPP Tape roll
8.	White stripping roll
9.	100 ml milkey white bottle round

6.6 Special precautions for disposal and other handling
.Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

Imported by:
Kenix Pharmaceutical Limited
78 Community Road, Off Ago Palace Way Okota
Lagos State Nigeria

Manufactured by:
M/s. HEALTH CARE FORMULATIONS PVT. LTD,
Survey No. C/8, SARDAR ESTATE, AJWA Road, CITY: VADODARA-390019,
GUJARAT STATE, INDIA