1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

UFOX SUSPENSION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml reconstitute suspension contains
Cefuroxime Axetil USP
Equivalent to Cefuroxime : 125 mg
Colour : Sunset Yellow FCF
Excipients : Q.S

3. PHARMACEUTICAL FORM

Dry Syrup
For oral administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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, tonsillitis and pharyngitis.
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.

4.2 Posology and method of administration

Adults: Most infections will respond to 250mg b.d. In mild to moderate lower respiratory tract infections e.g. bronchitis 250mg b.d. should be given. For more severe lower respiratory tract infections, or if pneumonia is suspected then 500mg b.d. should be given. For urinary tract infections a dose of 125mg b.d. is usually adequate; in pyelonephritis the recommended dose is 250mg b.d. A single dose of one gram is recommended for the treatment of uncomplicated gonorrhoea.
Method of administration: Oral

4.3 Contraindications

Cefuroxime Axetil products are contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use

Care should be taken with patients who have experienced an anaphylactic reaction to penicillin.
Cefuroxime does not interfere with enzyme-based tests for glucosuria. However this should not lead to false-positive results. It is recommended that either the glucose oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients treated with cefuroxime. In the ferricyanide test, cefuroxime may cause false -negative reactions. Some cephalosporins can cause a falsely high reading in the alkaline picrate assay for creatinine, although the degree of elevation is unlikely to be of clinical importance. It is possible that cefuroxime may also interfere with this determination. When possible, concomitant use of furosemide and cefuroxime should be avoided. If used together renal function should be monitored closely, since furosemide may enhance the nephrotoxic potential of the cephalosporins.

4.5 Interaction with other medicinal products and other forms of interaction

In common with other antibiotics, Ozax 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 cefuroxime axetil. This antibiotic does not interfere in the alkaline picrate assay for creatinine.

4.6 Pregnancy and lactation

Pregnancy
There is no experimental evidence of embryopathic or teratogenic effects attributable to cefuroxime axetil but, as with all drugs, it should be administered with caution during early months of pregnancy.
Lactation :Cefuroxime is excreted in human milk, and consequently caution should be exercised when cefuroxime axetil is administered to a nursing mother.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed. However, as this medicine may cause dizziness, patients should be warned to be cautious when driving or operating machiner

4.8 Undesirable effects

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
Hepatobiliary disorders
Common: Transient increasesof hepatic enzyme levels, [ALT (SGPT), AST (SGOT), LDH]
Very rare: Jaundice (predominantly cholestatic), hepatitis

4.9 Overdose

Overdosage of cephalosporins can cause cerebral irritancy leading to convulsions. Serum levels of cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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. Peak serum cefuroxime levels occur approximately 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 are reduced by dialysis.

5.3 Preclinical safety data

No inhouse preclinical safety data has been done.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose Granules*	IHS
Dextrose Anhydrous	BP
Sodium Citrate	BP
Aspartame	BP
Flavour Sweet Orange Dry	IHS
Flavour Vanilla Dry	IHS
Sucralose	BP
Flavour Pipermint Dry	IHS
Colour Sunset Yellow	IHS
Colloidal Anhydrous Silica	BP
Sodium Lauryl	BP
Purified Talc	BP
Citric Acid	BP
Sodium Chloride	BP
Xanthan Gum	USP
Polyethylene Glycol - 200	BP

6.2 Incompatibilities

NA

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light, heat and moisture.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

100 ml HDPE Bottle packed in printed carton along with package insert.

6.6 Special precautions for disposal and other handling

None Known.

7. MARKETING AUTHORISATION HOLDER

APPLICANT
VENCHURA PHARMACEUTICALS LIMITED,
5, MERCY ENELI STREET,

MANUFACTURER
RELAX BIOTECH PVT.LTD,
862/1, G.I.D.C., MAKARPURA, VADODARA-390010. GUJARAT, INDIA.

8. MARKETING AUTHORISATION NUMBER(S)