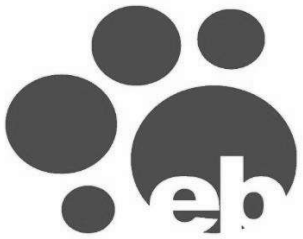

Evans Baroque Limited

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC) Zitclav Suspension

1. NAME OF THE MEDICINAL PRODUCT

ZITCLAV Dry syrup Cefuroxime 125 mg / Clavulanic Acid 31.25 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml reconstituted suspension contains:

Cefuroxime	125mg
Clavulanic acid	31.25mg
Excipients	q.s.
Colour: Sunsent Yellow	

3. PHARMACEUTICAL FORM

White coloured granular powder converted into orange colour suspension on addition of water

4. Clinical particulars

4.1 Therapeutic indications

ZITCLAV Dry syrup is indicated in children from 3 months to 12 years

4.2 Posology and method of administration

Posology

Pediatric population

ZITCLAV Dry syrup should not be used in children less than 3 months

Method of administration

Oral dosage form

4.3 Contradictions

It is contraindicated in patients with known allergy to Cefuroxime and clavulanic acid or to the cephalosporins group of antibiotics.

4.4 Special warnings and precautions for use

- Before therapy with ZITCLAV Dry syrup, inquiry should be made to determine if the patient has had previous hypersensitivity reaction to cephalosporins, penicillins or other drugs.
- Because cefuroxime is excreted in human milk, consideration should be given to discontinue nursing temporarily during treatment with cefuroxime
- Prescribing ZITCLAV in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increase the risk of the development of drug-resistance bacteria
- Cephalosporins, including cefuroxime, should be given with caution to patient receiving concurrent treatment with potent diuretics because these diuretics are suspected of adversely affecting renal function.

- Cefuroxime, as with other broad-spectrum antibiotics, should be prescribed with catioN in individuals with a history of colitics

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid- Concomitant administration of probenecid with cefuroxime axetil tablets increase the area under the serum concentration versus the time curve by 50%.

Antacid- Drugs that reduce gastric acidity may result in a lower availability of ZITCLAV DS compared with that of fasting state and tend to cancel the effect of postprandial absorption.

Oral contraceptive- In common with other antibiotics, cefuroxime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of of combined oral estrogen/progesterone.

4.6 Pregnancy and Lactation

Pregnancy

While all antibiotics should be avoided in the first trimester if possible. However, ZITCLAV can be safely used in later pregnancy to treat urinary and other infection.

Lactation

Cefuroxime is excreted in human milk; consideration should be given to discontinue nursing temproraily during therapy.

Fertility

No proven adverse effect on fertility in men or women.

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.

4.8 Undesirable effects

Generally Cefuroxime and Clavulanic acid are well tolerated. However, a few side effects like nausea, vomitting, diarrhea, abdominal discomfort or pain may occur. As with other broad spectrum antibiotics, prolonged administration of cefuroxime and clavulanic acid combination may result in overgrowth of non-susceptible microorganisim. Rare side effects are renal dysfunction, anaphylaxis, pruritics, rash and serum sickness like urticaria may appear.

4.9 Overdose

Overdose can cause cerebral irritation leading to convulsions. In this case, serum levels can be reduced by hemodialysis and peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

ZITCLAV is a second generation cephalosporins with an ATC code of J01DC52.Cefuroxime has bactericidal activity against a wide range of common pathogens, including beta-lactamase producing strains. The bactericidal action of Cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.Cefuroxime has good stability to bacterial beta-lactamases. Clavulanic acid is a naturally derived beta lactamese inhibitor produced by Streptomyces ctavuligerus. Clavulanic acid binds to and inactivates them thus preventing the destruction of cefuroxime that is a substrate for this enzyme. It has poor Intrinsic antimicrobial activity, but It is an irreversible binder of beta-lactam

produced by a wide range of gram positive and gram negative microorganism.Thus, the combination of cefuroxime and clavulanic acid (5-lactamase inhibitor) provides a solution for treatment of bacterial Infections caused by beta lactam resistant pathogens.

Cefuroxime exhibits time-dependent killing, meaning:Effectiveness depends on the time that drug concentrations remain above the minimum inhibitory concentration (MIC) of the pathogen.Thus, maintaining levels above MIC for a sufficient duration is key for clinical efficacy.

Cefuroxime is clinical effective against Respiratory tract infections Urinary tract infections Skin and soft tissue infection Ear, nose, and throat infections Lyme disease (early stage) and it is well tolerated.

5.2 Pharmacokinetic properties

After oral administration, cefuroxime axetil is well absorbed from the gastrointestinal tract, and rapidly hydrolyzed by nonspecific esterases in the intestinal mucosa and blood to cefuroxime.Absorption of the Suspension is greater when taken after food. Peak serum concentrations are achieved 2-3 hrs after an oral dose.Serum levels of 2.37 mcg/mL are obtained from oral administration of cefuroxlme axetil 125 mg. About 50% of the drug is protein bound. It is widely distributed In the body, including pleural fluid, sputum, bone, synovial fluid, aqueous humor and cerebrospinal fluid when meninges are inflamed. The axetil moiety is metabolized to acetaldehyde and acetic acid. Cefuroxlme is excreted unchanged In the urine and approximately 50% of the administered dose is recovered In the urine within 12 hrs. Mean elimination half-life is 1.2 hrs.
Combining Clavulanic acid with beta-lactam antibiotic cause no appreciable alteration of the pharrnacokinetics of either drug compared with their separate administration.On administration of clavulanate potassium 31.25 mg, the maximum plasma concentration obtained Is 0.78 mcg/mL and approximately 30 to 40% of a dose of clavulanic acid is excreted in the urine, as clavulanic acid, during the first six hours after administration.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, mutagenecity, carcinogenic potential, toxicity to reproduction and development done using animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Kyron T-114C IHS
Purified Water BP
Mannitol BP
Silicon Dioxide(Syloid AL-1 FP) USP
Xanthan Gum (FNCS) BP
Aspartame BP
Sodium Methyl HydroxyBenzoate BP
Sodium Propyl HydroxyBenzoate BP
Peppermint Encapsulated Dry FlavourIHS
BTM Dry Flavour IHS
Sucralose BP
Colloidal Anhydrous Silica BP
Sunset Yellow IHS
Sodium Citrate BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25°C away from light.Store in a refrigerator between 2-8`C after reconstitution and use within 7days.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

60 ml amber bottle with a white plastic cap in a carton along with pack insert.

6.6 Special precautions for disposal <and other handling>

No special requirements

7 APPLICANT

Evans Baroque Nigeria Limited

Km 32, Lagos – Badagry Expressway,

Agbara Industrial Estate, Agbara,

Ogun State, Nigeria

info@evansbaroque.com

MANUFACTURER

Baroque Pharmaceuticals Pvt. Ltd

192/2 & 3, 19-/1 and 202/9, Sokhada – 388620,

Ta. Khambhat, Dist. Anand, Gujurat,

India