

# Vexotil<sup>TM</sup>

## Cefuroxime

### COMPOSITION:

**Vexotil<sup>TM</sup> 250 mg Tablet:** Each film coated tablet contains Cefuroxime Axetil BP equivalent to Cefuroxime 250 mg.

**Vexotil<sup>TM</sup> 500 mg Tablet:** Each film coated tablet contains Cefuroxime Axetil BP equivalent to Cefuroxime 500 mg.

**Vexotil<sup>TM</sup> Powder for Suspension:** Each 5 ml reconstituted suspension contains Cefuroxime Axetil BP equivalent to Cefuroxime 125 mg.

### PHARMACOLOGY:

Cefuroxime is a 2nd generation Cephalosporin antibiotic with broad spectrum bactericidal activity against both gram-positive and gram-negative bacteria including  $\beta$ -lactamase strains. Cefuroxime interferes with the synthesis of bacterial cell wall by attaching to Penicillin Binding Protein (PBP) and inhibiting peptidoglycan synthesis, thus causing change to the bacterial cell wall.

### INDICATIONS:

**Vexotil<sup>TM</sup>** (Cefuroxime) is indicated for the treatment of the following infections caused by the susceptible micro-organisms:

- Upper respiratory tract infections such as otitis media, sinusitis, tonsillitis and pharyngitis
- Lower respiratory tract infection such as acute bronchitis, acute exacerbations of chronic bronchitis and pneumonia
- Skin and soft tissue infections such as furunculosis, pyoderma, and impetigo
- Genito-urinary tract infections such as pyelonephritis, urethritis, and cystitis
- Gonorrhoea such as acute uncomplicated gonococcal urethritis and cervicitis
- Early Lyme disease & subsequent prevention of late Lyme disease

### DOSAGE & ADMINISTRATION:

**Route of administration:** **Vexotil<sup>TM</sup>** tablet and PFS should be administered orally according to dosage guidelines.

#### Adults:

- The usual dose is 250 mg twice daily for most infections
- In mild to moderate lower respiratory tract infections e.g. bronchitis: 250 mg twice daily
- In more severe lower respiratory tract infections, or suspected pneumonia: 500 mg twice daily
- In urinary tract infections: 125 mg twice daily
- In pyelonephritis: 250 mg twice daily
- In uncomplicated gonorrhoea: A single dose of one gram is recommended
- Lyme disease in adults & children over the age of 12 years: The recommended dose is 500 mg twice daily for 20 days

#### Children:

- The usual dose is 125 mg or 10 mg/kg body weight twice daily to a maximum of 250 mg daily
- Children aged two years or older with otitis media: 250 mg or 15 mg/kg body weight twice daily to a maximum of 500 mg daily

There is no data in children under three months of age.

Cefuroxime should be taken after food for optimum absorption.

### CONTRAINDICATIONS:

Patients with known hypersensitivity to cephalosporin group of antibiotics.

### WARNINGS & PRECAUTIONS:

Special care is indicated in patients who have experienced all allergic reaction to penicillins or other cephalosporin antibiotics.

### SIDE-EFFECTS:

The drug is generally well tolerated.

**Common side effects:** The most frequent side effects observed are diarrhoea, nausea, vomiting, skin rashes, urticaria, pruritus.

**Rare side effects:** Restlessness, confusion, colitis, neutropenia, serum sickness, headache and dizziness.

### USE IN PREGNANCY & LACTATION:

**Use in pregnancy:** Pregnancy category B. Cefuroxime should be administered with caution during pregnancy.

**Use during lactation:** Cefuroxime is excreted in human milk and consequently caution should be exercised when Cefuroxime is administered to nursing mother.

### DRUG INTERACTIONS:

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

### OVERDOSE:

Overdose of cephalosporins can cause cerebral irritation leading to convulsions.

### STORAGE:

**Tablet:** Protect from light exposure. Store in cool & dry place at a temperature not exceeding 30°C. Keep out of reach of children.

**Powder for Suspension:** Prior to reconstitution, store below 30°C. After reconstitution, the suspension may be kept for 14 days under refrigeration or at room temperature.

### PACKING:

**Vexotil<sup>TM</sup> 250 mg Tablet:** Each box contains 14's tablets in Alu-Alu blister strip.

**Vexotil<sup>TM</sup> 500 mg Tablet:** Each box contains 14's tablets in Alu-Alu blister strip.

**Vexotil<sup>TM</sup> PFS:** Each bottle contains dry powder for preparation of 70 ml suspension.

Manufactured by:

Apex Pharma Ltd. for

**Organic Health Care Ltd.**

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