

## COMPOSITION :

### Each film-coated tablet contains:

Cefpodoxime Proxetil USP		
equivalent to Cefpodoxime	.....	200 mg
Clavulanic Acid	.....	125 mg



**ZIPOTIL- CV:** A Combination of Cefpodoxime (third generation oral cephalosporin) and Clavulanic Acid (a beta lactamase inhibitor) is used for the treatment of urinary tract infections, pneumonia, bronchitis, gonorrhea, and multiple other infections.

### MECHANISM OF ACTION:

Cefpodoxime, a third generation semi-synthetic cephalosporin, exhibits activity against several Gram positive as well as Gram negative microorganisms. This compound is also stable in beta lactamase environment. Cefpodoxime exhibits exceptional activity against methicillin susceptible Staphylococci, Streptococcus pneumoniae, Haemophilus influenzae, Neisseria spp, and Moraxella catarrhalis, which are referred as the most common hospital acquired and community acquired infections.

Clavulanic Acid, a natural inhibitor of beta lactamase, which are produced by Streptomyces clavuligerus binds to beta lactamase moieties and inactivates them, thus restricting the cefpodoxime destruction. Clavulanic acid has very little antimicrobial activity.

### PHARMACOKINETICS:

**Cefpodoxime:** Bioavailability of cefpodoxime is 50% in fasting subjects and it increases in presence of food. Peak plasma concentration of Cefpodoxime 200 mg single dose is 2.18 mcg/ml.

The Drug is well distributed after oral administration. Cefpodoxime reaches therapeutic concentrations in respiratory tract and genito-urinary tracts and bile. Protein binding of cefpodoxime ranges from 20 to 30 %. The plasma half life of cefpodoxime is about 2 to 3 hours and is prolonged in patients with impaired renal function. Cefpodoxime is excreted unchanged in urine.

### Clavulanic Acid:

Clavulanic acid is well absorbed after oral administration. Peak plasma concentration of Clavulanic acid 125 mg single dose is 2.2 mcg/ml. It is distributed completely after oral administration. Protein binding of clavulanic acid is about 30 %. The plasma half life of clavulanic acid is one hour. About 60 % of clavulanic acid is excreted unchanged in urine. The clavulanic acid component in the drug combination protects cefpodoxime from degradation by  $\beta$ -lactamase enzymes, and effectively extends the antibiotic spectrum of cefpodoxime to include many bacteria that are normally resistant to cefpodoxime and other  $\beta$ -lactam antibiotics.

### INDICATIONS

**ZIPOTIL-CV** is indicated in the following infections when caused by susceptible organisms

- Acute bacterial exacerbations of chronic bronchitis
- Acute community acquired Pneumonia
- Upper and lower respiratory tract infections
- Skin and soft tissue infections
- Urinary tract infections
- Pharyngitis and/or tonsillitis
- General gonorrhea (men and women) and rectal gonococcal infections (women).

### HIGHLIGHTS:

- ZIPOTIL-CV is a combination of two drugs and is effective against multiple infection types.
- Clavulanic acid component protects degeneration of cefpodoxime in presence of  $\beta$ -lactamase enzymes, and increases the antibiotic spectrum.
- Clavulanic acid in ZIPOTIL-CV, prevents the resistance to Cefpodoxime that may increase with continuous usage of the drug.
- ZIPOTIL-CV has shown effectiveness against multiple Gram-positive and Gram-negative bacteria.
- Cefpodoxime is generally well tolerated.

### ADVERSE EFFECTS:

#### Cefpodoxime

Incidence greater than 1% include #Diarrhea: 7%; Nausea: 3.3%; Vaginal Fungal Infections: 1%; Vulvovaginal Infections: 1.3%; Abdominal Pain: 1.2%; and Headache: 1%

Number of diarrhea or loose stools were dose related: decreasing from 10.4% of patients receiving 800 mg per day to 5.7% for those receiving 200 mg per day. Of patients with diarrhea, 10% had C. difficile organism or toxin in the stool.

Other adverse events consists of difficulty breathing or swallowing, Hives, Itching, Mild skin rash, Painful mouth or throat sores, Severe skin rash, Sore throat, Unusual bleeding or bruising, Upset stomach, Vaginal infection, Vomiting, and Wheezing

**Clavulanic Acid:** Side effects include bloody diarrhea, bloody urine, painful or difficult urination, unusual weakness, easy bleeding and bruising, confusion, dry mouth, increased urination, chills, body aches, fever, sore throat, headache, seizures, chest pain and irregular heartbeat. These side effects are very rare and do not affect a large amount of users. Treatment should not normally exceed 14 days.

**PACKAGING INFORMATION:**

ZIPOTIL- CV is available in a strip of 6 Tablets.