

# **ADVOJET- CL TAB.**

## **Composition :**

Each film coated tablet contains :

Cefixime I.P. as Trihydrate eq. to Anhydrous Cefixime	200mg.
Diluted Potassium Clavulanate I.P. eq. to Clavulanic Acid	125mg.

## **DESCRIPTION :**

**CEFIXIME** : Cefixime is a third generation cephalosporin antibiotic useful for the treatment of a number of bacterial infections. It is a broad spectrum cephalosporin antibiotic and is commonly used to treat bacterial infections of the ear, urinary tract, and upper respiratory tract. The chemical formula of Cefixime is  $C_{16}H_{15}N_5O_7S_2$ .

## **PHARMACOLOGY :**

### **Pharmacodynamics :**

The bactericidal action of Cefixime is due to the inhibition of cell wall synthesis. It binds to one of the penicillin binding proteins (PBPs) which inhibit the final transpeptidation step of the peptidoglycan synthesis in the bacterial cell wall, thus inhibiting biosynthesis and arresting cell wall assembly resulting in bacterial cell death. Cefixime is highly stable in the presence of beta-lactamase enzymes. As a result, many organisms resistant to penicillins and some cephalosporins due to the presence of beta-lactamases may be susceptible to cefixime.

### **Pharmacokinetic :**

**Absorption** : Only 40-50% is absorbed from the GI tract (oral). Rate may be decreased if taken with food. Absorption from oral suspensions than tablet is more.

**Distribution** : It has high concentrations in bile and urine. It can cross the placenta and its protein binding capacity is 65%.

It is always better to perform appropriate cultures and susceptibility studies to determine the causative organism and its sensitivity to cefixime.

**Bioavailability** : 40% to 50%.

**Protein binding** : Approximately 60%.

**Biological half life** : Average 3 to 4 hours.

**Excretion** : Renal and biliary.

**Clavulanic acid** : Clavulanic acid is a  $\beta$ -lactam drug that functions as a mechanism-based  $\beta$ -lactamase inhibitor. While not effective by itself as an antibiotic, when combined with penicillin-group antibiotics, it can overcome antibiotic resistance in bacteria that secrete  $\beta$ -lactamase, which otherwise inactivates most penicillins. Clavulanic acid is derived from the *Streptomyces clavuligerus* which produces clavulanic acid. With the  $\beta$ -lactam like structure, clavulanic acid looks structurally similar to penicillin. Chemical formula of Clavulanic acid is  $C_8H_9NO_5$ .

## PHARMACOLOGY :

### Pharmacodynamic :

Clavulanic acid has negligible intrinsic antimicrobial activity, despite sharing the  $\beta$ -lactam ring that is characteristic of  $\beta$ -Lactam antibiotics. However, the similarity in chemical structure allows the molecule to interact with the enzyme  $\beta$ -Lactamase secreted by certain bacteria to confer resistance to  $\beta$ -lactam antibiotics.

### Pharmacokinetic :

Bioavailability : Well absorbed. The mean peak plasma concentration of clavulanic acid is 0.29 hour.

Metabolism : Hepatic.

Biological half life : Approximately 1 hour.

Excretion : Renal (30 – 40 %)

## ADVOJET– CL TAB.

**Advojet – CL Tab.** is combination of Cefixime Trihydrate and Clavulanic Acid.

Cefixime Trihydrate is a semisynthetic, oral, third generation cephalosporin antibiotic. It is effective against Gram +ve, Gram –ve and anaerobic bacteria including beta – lactamase producing strains. It acts by inhibition of bacterial cell wall synthesis.

Clavulanic Acid is a beta lactamase inhibitor produced by Streptomyces Clavuligerus. Clavulanic Acid is an irreversible inhibitor of intracellular and extracellular beta lactamase. The combination of Cefixime Trihydrate and Clavulanic Acid is useful in treatment of bacterial infections caused by beta lactamase resistant strain.

## INDICATIONS :

This combination of drug should be used only to treat or prevent infections that are proven or strongly suspected to be susceptible bacteria to Cefixime Trihydrate and Clavulanic Acid.

### **Advojet – CL is indicated for the treatment of :**

1. Uncomplicated Urinary Tract Infections caused by Escherichia Coli and Proteus Mirabilis.
2. Otitis Media caused by Haemophilus Influenzae, Moraxella Catarrhalis and S.Pyogenes.
3. Acute Bronchitis and Acute Exacerbations of Chronic Bronchitis caused by Streptococcus Pneumonia, and Haemophilus Influenzae.
4. Pharyngitis and Tonsillitis caused by S.Pyogenes.
5. Uncomplicated gonorrhoea caused by Neisseria Gonorrhoeae.

## CONTRAINDICATION :

Cefixime is contraindicated in patients with known sensitivity or allergies to cephalosporin class of antibiotics. As Cefixime is a third generation cephalosporin, it is not contraindicated for patients with a true penicillin allergy.

## DOSAGE :

**Adults and Children over 10 Years:** One tablet twice daily. The usual course of treatment is 7 days. This may be continued for up to 14 days if required.

## SIDE EFFECT :

The most frequent side effects seen with Cefixime-Clav are diarrhea and stool changes. Events like nausea/vomiting, transient elevation in liver transaminases, alkaline phosphatase and jaundice can also occur.

Thrombocytosis, thrombocytopenia, leucopenia, hypere-osinophilia, neutropenia and agranulocytosis may also occur.

Other adverse events that may occur are abdominal pain, abdominal cramps, flatulence, indigestion headache, vaginitis, vulvar itch, rash, hives, itch, dysuria, chills, chest pain, shortness of breath, mouth ulcers, swollen tongue, sleepiness, thirst, anorexia.

## DRUG INTERACTIONS :

**Carbamazepine:** Elevated carbamazepine levels have been reported when Cefixime is administered concomitantly.

**Warfarin and Anticoagulants:** Increased Prothrombin time, with or without clinical bleeding, been reported when cefixime is administered concomitantly.

**Oral Contraceptives:** Cefixime may interfere with the effectiveness of birth control pills.

**Glucose Test:** A false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets.

**Alcohol :** No major interaction has been observed between cefixime with clave and alcohol.

## WARNINGS / PRECAUTIONS :

1. Caution should be exercised if the individual had complained of previous hypersensitivity reactions to cephalosporins, penicillins or other drugs.
2. Like other broad-spectrum antibiotics Cefixime should be prescribed with caution in individuals with a history of colitis.
3. Increase of prothrombin times may occur and therefore care should be taken in patients receiving anticoagulant therapy.
4. There is no adequate and well-controlled studies on this combination use in pregnant and nursing women have been reported , therefore Advojet-CL Tab. should not be used in pregnancy or in nursing mothers unless considered it much essential than adverse effects by the physician.

## OTHER PRECAUTION :

It may reduce platelet counts, avoid injury or bruising.  
Avoid any vaccination during the treatment.

## STORAGE :

Store below 25° Celsius, protected from light & moisture.

## PRESENTATION :

Advojet-CL tablet is available 1\*6 in a strip and 10 strips in a carton.