

# CefofAL-200

(Cefixime and Ofloxacin tablet)

## Each Tablet Contains:

Cefixime IP .....200mg (As trihydrate)

Ofloxacin IP .....200mg

Excipients.....q.s.

## Clinical Pharmacology:

**Cefixime:** Cefixime is a third-generation cephalosporin antibiotic with a broad spectrum of activity. It works by inhibiting bacterial cell wall synthesis, leading to cell lysis and death. Cefixime is effective against a variety of Gram-positive and Gram-negative bacteria and is stable in the presence of beta-lactamase enzymes.

**Ofloxacin:** Ofloxacin is a fluoroquinolone antibiotic that inhibits bacterial DNA gyrase and topoisomerase IV, which are necessary for DNA replication, transcription, and repair. This results in the inhibition of bacterial growth. Ofloxacin has a broad spectrum of activity against both Gram-positive and Gram-negative bacteria, as well as some anaerobes and atypical bacteria.

## Indications:

- Acute bacterial infections of the respiratory tract
- Urinary tract infections (UTIs)
- Gonorrhoea
- Otitis media
- Skin and soft tissue infections
- Gastrointestinal infections such as infectious diarrhea
- Bone and joint infections

## Contraindications:

Hypersensitivity to cefixime, ofloxacin, other cephalosporins, or quinolones  
Patients with a history of severe allergic reactions (e.g., anaphylaxis) to beta-lactam antibiotics.

Children and adolescents undergoing growth (due to quinolone-induced cartilage damage).

Patients with a history of tendon disorders related to quinolone use.

## Precautions and Warnings:

- **Tendinitis and Tendon Rupture:** Quinolones, including ofloxacin, may increase the risk of tendinitis and tendon rupture in all ages. Discontinue if tendinitis occurs.
- **Hypersensitivity Reactions:** Serious allergic reactions may occur in patients taking cephalosporins or fluoroquinolones.
- **CNS Effects:** Fluoroquinolones, including ofloxacin, can cause CNS side effects such as seizures, tremors, confusion, and hallucinations.
- **QT Prolongation:** Ofloxacin may cause QT interval prolongation; use with caution in patients with cardiac conditions.
- **Clostridium difficile-associated diarrhea (CDAD):** This may occur with antibiotic treatment and should be considered in patients presenting with diarrhea after administration.

#### **Drug Interactions:**

- **Antacids and Sucralfate:** These can reduce the absorption of ofloxacin. They should be taken at least 2 hours before or after taking ofloxacin.
- **Warfarin:** Increased anticoagulant effects may occur when cefixime is combined with warfarin. Monitoring of INR is recommended.
- **Theophylline and NSAIDs:** May increase the risk of CNS stimulation, including seizures, when used concurrently with ofloxacin.

#### **Adverse Effects:**

Cefixime: Common side effects include diarrhea, nausea, abdominal pain, dyspepsia, and hypersensitivity reactions such as rash or pruritus.

Ofloxacin: Common adverse effects include gastrointestinal disturbances (nausea, vomiting, diarrhea), headache, dizziness, and sleep disturbances. Rarely, it can cause serious side effects such as tendinitis, tendon rupture, and peripheral neuropathy.

#### **Overdosage:**

Cefixime Overdose: Symptoms may include severe gastrointestinal disturbances and neurological symptoms like seizures.

Ofloxacin Overdose: Symptoms include dizziness, confusion, seizures, and gastrointestinal issues. Provide supportive care and symptomatic treatment.

#### **Route of Administration:**

Tablets should be swallowed whole with water. Do not crush or chew the tablet.

#### **SCHEDULE H PRESCRIPTION DRUG CAUTION:**

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

**Dosage:** As directed by a physician.

**Storage:** Store in a cool, dry place below 25°C. Protect from light and moisture. Keep out of reach of children

**Presentation:** Available as a strip of 10X10 tablets per pack.



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