# TrioClav®

Cefpodoxime & Clavulanic Acid Film Coated Tablet

## DESCRIPTION

**Trioclav®** is a combined preparation of cefpodoxime & clavulanic acid. Cefpodoxime, a third generation semi-synthetic cephalosporin, exhibits activity against several Gram positive as well as Gram negative microorganisms. 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 is a natural inhibitor of beta lactamase, which are produced by Streptomyces clavuligerus. It binds to beta lactamase moieties and inactivates them, thus restricting the cefpodoxime destruction. Clavulanic acid has very little antimicrobial activity.

## INDICATIONS

- 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)
- Acute maxillary sinusitis

**Adult or Children:**

| Infection | Total Daily Dosage | Dosage Frequency | Duration (days) |
|---|---|---|---|
| Pharyngitis and/or tonsillitis | 200 mg | 100 mg Q 12 hrs | 5 to 10 |
| Acute community acquired Pneumonia | 400 mg | 200 mg Q 12 hrs | 14 |
| Acute bacterial exacerbations of chronic bronchitis | 400 mg | 200 mg Q 12 hrs | 10 |
| Uncomplicated gonorrhea (men and wome rectal gonococcal infections (women) | 200 mg | Single dose | N/A |
| Skin and soft tissue infections | 800 mg | 400 mg Q 12 hrs | 7 to 14 |
| Uncomplicated urinary tract infection | 200 mg | 100 mg Q 12 hrs | 7 |
| Acute maxillary sinusitis | 400 mg | 200 mg Q 12 hrs | 10 |

## CONTRAINDICATIONS

It is contraindicated in patients with a known hypersensitivity to cephalosporin group of antibiotics and clavulanic acid.

## USE IN PREGNANCY & LACTATION

No adequate and well-controlled studies in pregnant women have been reported so Cefpodoxime-Clavulanic acid should therefore not be used in pregnancy or in nursing mothers unless considered essential by the physician.

## PRECAUTIONS & WARNINGS

Cross hypersensitivity in penicillin sensitive patients, leading to serious acute hypersensitivity reactions may need treatment with epinephrine along with other emergency measures such as intravenous fluids, oxygen, airway management, and intravenous antihistamine, as clinically indicated.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antimicrobial agents, including cefpodoxime and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted, as clinically indicated.

In patients with transient or persistent reduction in urinary output due to renal insufficiency, the total daily dose of cefpodoxime should be reduced because high and prolonged serum antibiotic concentrations can occur in such individuals following usual doses. Cefpodoxime, like other cephalosporins, should be administered with caution to patients receiving concurrent treatment with potent diuretics.

## SIDE EFFECTS

The most frequent side effects seen with Cefpodoxime-Clavulanic acid are diarrhea and stool changes. Others are nausea/vomiting, vaginal fungal infection, abdominal pain.

## PHARMACEUTICAL PRECAUTIONS

Keep in a cool (below 25° C) and dry place, away from light. Keep out of reach of children.

## PACKAGING

**Trioclav® 200 FCT**: Box containing 1 strip of 7 tablets or 2 strips of 7 tablets each. Each film coated tablet contains Cefpodoxime Proxetil USP equivalent to Cefpodoxime 200 mg and diluted Potassium Clavulanate BP equivalent to Clavulanic Acid 125 mg.

SK+F

Manufactured by
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