

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 gonorrhoea (men and women) and rectal gonococcal infections (women)
- Acute maxillary sinusitis

DOSAGE AND ADMINISTRATION

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 gonorrhoea (men and women) 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

Do not store above 25° C temperature. Keep away from light and wet place. 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

ESKAYE PHARMACEUTICALS LTD.

TONGI, GAZIPUR, BANGLADESH

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