

DENTACLOX CAPSULES

Composition:

Each Capsule contains:

Amoxicillin [as trihydrate]---- 250mg

Cloxacillin [as sodium] -----250mg

Lactic Acid Bacillus -----100 million spores

Pharmacology

Amoxicillin is a semi-synthetic broad spectrum antibiotic, with bactericidal activity against many Gram-positive and Gram-negative microorganisms. Cloxacillin sodium is an antibacterial agent of the isoxazolyl penicillin series. It is penicillinase-resistant, acid-resistant and is suitable for oral administration.

DENTACLOX produces its bactericidal action by interfering with cell wall synthesis. The drugs in this class are highly resistant to inactivation by staphylococcal penicillinase and are active against penicillinase producing and non-penicillinase producing strains of *Staphylococcus aureus*.

The antimicrobial spectrum of **DENTACLOX** includes *Staphylococcus* species, *Streptococcus* species, *Moraxella catarrhalis*, *Escherichia coli*, *Haemophilus influenzae*, *Enterococcus faecalis*, *Neisseria gonorrhoeae* and *Proteus mirabilis*.

DENTACLOX is stable in the presence of gastric acid and is rapidly absorbed after oral administration. It diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. Most of the **DENTACLOX** is excreted unchanged in the urine; its excretion can be delayed by concurrent administration of probenecid. Orally administered doses of 250 and 500 mg **DENTACLOX** result in average peak blood levels 1-2 hours after administration in the range of 3.5-5.5 mg/ml and 5.5-7.5 mg/ml respectively.

Indications

DENTACLOX is indicated for the treatment of following infections when caused by susceptible microorganisms:

1. 1. Oro-dental Infections:

- a) a) Gingivitis
- b) b) Dental Caries
- c) c) Periodontitis
- d) d) Periapical abscess
- e) e) Pulpitis

2. 2. Post-surgical prophylaxis of infection, wherever use is noticed.

Contraindications

A history of allergic reaction to any of the penicillins is a contraindication to the use of **DENTACLOX**.

Precautions

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, **DENTACLOX** should be discontinued and appropriate therapy instituted.

Pseudomembranous colitis has been reported with almost all antibacterial agents, and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Pregnancy & Lactation

There are no adequate and well-controlled studies in pregnant women with **DENTACLOX**. Since animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Caution should be exercised when **DENTACLOX** is administered to a nursing woman.

Drug Interactions

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased and prolonged blood levels of amoxicillin.

Chloramphenicol, macrolides, sulfonamides and tetracyclines may interfere with the bactericidal effects of penicillin. This has been demonstrated in vitro; however, the clinical significance of this interaction is not well documented.

Adverse Reactions

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins and in those with a history of allergy, asthma, hay fever, or urticaria. Common adverse events reported with the use of **DENTACLOX** are on the gastrointestinal system and include nausea, vomiting, diarrhea, and Pseudomembranous colitis.

Onset of Pseudomembranous colitis symptoms may occur during or after antibiotic treatment.

Dosage & Administration

The usual recommended dose of **DENTACLOX** is one capsule tid. **DENTACLOX** capsules may be given without regard to meals.

Presentation

DENTACLOX is available in a strip of 10 capsules.