CLOXACILLIN SODIUM

OXCIL

500 mg Capsule

ANTIBACTERIAL

PRODUCT DESCRIPTION:
500 mg Capsule - White to creamy white powder in gray cap/yellow body EGC size "0"

FORMULATION:
Each capsule contains:
Cloxacillin (as Sodium) , USP ..... 500 mg

PHARMACODYNAMICS:
Cloxacillin sodium is a bactericidal antibiotic which include natural and semisynthetic derivatives. This agent contains the 6-ß aminopenicillinic acid nucleus and have similar mechanism of action. All of the penicillin share cross-allergenicity. The significant differences among agents include: Resistance to gastric acid inactivation; resistance to inactivation by penicillinase; and spectrum of antimicrobial activity.

PHARMACOKINETICS:
Mechanism :
Cloxacillin sodium inhibits the biosynthesis of cell wall mucopeptide. It is a bactericidal agent against sensitive organisms when adequate concentrations are reached, and it is most effective during the stage of active multiplication. Inadequate concentrations may produce only bacteriostatic effects.
Absorption:
Absorption of most penicillins is affected by food: These medications are best taken on an empty stomach, 1 hour before or 2 hours after meals.
Excretion: Penicillins are excreted largely unchanged in the urine by glomerular filtration and active tubular secretion. Non renal elimination includes hepatic inactivation and excretion in bile; this is only a minor route for all penicillins except nafcillin and oxacillin. Excretion by renal tubular secretion can be delayed by coadministration of probenecid. Excretion is delayed in neonates and infants. Elimination half life of most penicillins is short (less than 1 hour); for ampicillin it is slightly longer, impaired renal functions prolongs the serum half-life of penicillins eliminated primarily by renal secretions. The half-life is not greatly excreted for nafcillin, oxacillin, cloxacillin and dicloxacillin due to increase biotransformation biliary excretion. Biliary excretion of azlocillin is reduced in patients with common bile duct obstruction. Because piperacillin is excreted biliary and renal routes, it can be used safely in appropriate dosage in patients with severe renal impairment and in the treatment of hepato biliary infections.

INDICATIONS:
For the treatment of infections due to staphylococci resistant to benzylpenicillin, also used for mixed staphylococcal infections when the staphylococci are penicillin resistant.

DOSAGE AND MODE/ROUTE OF ADMINISTRATION:
Complete full course of therapy. Take on empty stomach 1 hour before or 2 hours after meals. Take each dose with a full glass of water, not fruit juice or carbonated beverage (cloxacillin, penicillin).Consult physician before taking additional medication (e.g. antacids, laxatives, vitamins).Take at even intervals, preferably around the clock. Notify physician if skin rash, itching hives or severe diarrhea occurs.
Therapy may be initiated prior to obtaining results of bacteriologic studies when there is reason to believe the causative organisms may be susceptible. Once results are known, adjust therapy.
Dosage for any individual patient must take into consideration the severity of infection, the susceptibility of the organism causing the infection and the status of the patient's host defense mechanism. Duration of therapy depends on the severity of the infection.
Continue all infections for a minimum of 48 hours to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. A minimum of 10 days treatment is recommended for any infection caused by group A Beta-hemolytic streptococci to prevent the occurrence of acute rheumatic fever or acute glomerulonephritis.
Patients with a history of rheumatic fever and receiving continuous prophylaxis may harbor increased numbers of penicillin-resistant organisms, consider use of another prophylactic anti-infective agent. If penicillin is used in these patients at surgery, interrupt the regular rheumatic fever program 1 week prior to surgery. At time of surgery, reinstitute penicillin as a prophylactic measure against hazards of surgically-induced bacteremia.
Adult: 1 capsule every 6 hours should be taken 1 hour before meals or 2 hours after meals or as prescribed by the physician.

CONTRAINDICATIONS:
History of hypersensitivity to penicillin or cephalosporins. Do not treat severe pneumonia, emphysema, bacteremia, pericarditis, meningitis and purulent or septic arthritis with oral penicillin during acute stage.

PREGNANCY AND LACTATION:
Category B. There are no adequate or well controlled studies in pregnant women. Penicillins cross the placenta. Use during pregnancy only if clearly needed.
Penicillins are excreted in breastmilk in low concentrations; use may cause diarrhea, candidiasis or allergic response in the nursing infant.

WARNINGS:
Hypersensitivity (estimated incidence, 1% to 10%); Seriously and occasionally fatal immediate hypersensitivity reactions have been reported . The incidence of anaphylactic shock is between 0.15% and 0.04%. Anaphylactic shock resulting in death has occurred in approximately 0.002% of the patients treated. Although anaphylaxis is more frequent following parenteral therapy, it may occur with oral use. Accelerated reactions (urticaria and occasionally laryngeal edema) and delayed reactions (most commonly involving the skin and mucous membrane) may also occur. These reactions are likely to be immediate and severe in penicillin sensitive individuals with history of atopic conditions. Before therapy, inquire about previous hypersensitivity reactions to penicillins, cephalosporins and other allergens. Skin testing with benzylpenicilloy-polylysine may be used to evaluate penicillin hypersensitivity. Individuals with a history of penicillin hypersensitivity have experienced severe reactions when treated with cephalosporins. The incidence of cross-allergenicity between penicillins and cephalosporins is estimated to range from 5% to 16%. Urticaria, other skin rashes and serum sickness like reactions may be controlled by antihistamines and, if necessary, corticosteroids. Discontinue use unless the condition treated is life-threatening and amenable only to penicillin therapy. Serious anaphylactoid reactions require emergency measures.
Use in neonates: Penicillins are excreted largely unchanged by the kidney. Because of incompletely developed renal function in infants, the rate of elimination will be slow. Use caution in administering to newborns and evaluate organ function frequently.

ADVERSE DRUG REACTION:
The most common adverse effects of Cloxacillin are hypersensitivity reactions, especially skin rashes; anaphylaxis occasionally occurs and has sometimes been fatal. Other adverse effects have generally been associated with large intravenous doses of benzylpenicillin; patients with impaired renal function are also at increased risk. These adverse effects include haemolytic anaemia and neutropenia, both of which might have some immunological basis; prolongation of bleeding time and defective platelet function; convulsion and other signs of Central Nervous System toxicity (encephalopathy has followed intrathecal administration and can be fatal); and electrolyte disturbances because of the administration of large amounts of potassium of sodium when Cloxacillin sodium, respectively are administered. Hepatitis and cholestatic jaundice have been reported rarely with some penicillins, notably penicillinase resistant penicillins such as flucloxacillin and oxacillin, and also combination of amoxicillin or ticarcillin with clavulanic acid. Nephropathy and interstitial nephritis, which may have some immunological basis, have been especially associated with meticillin, but may be produced by other penicillins. Some patients with syphilis and other spirochaete infections may experience a Jarisch-Herxheimer reaction shortly after starting treatment with penicillin, which is probably due to the release of endotoxins from the killed treponemes and should not be mistaken for a hypersensitivity reactions. Symptoms include fever, chills, headache, and reactions at the side of the lesions. The reactions can be dangerous in cardiovascular syphillis, or where there is a serious risk of increased local damage, such as with optic atrophy. Gastrointestinal effects such as diarrhea and nausea are the most common adverse effects following oral administration of benzylpenicillin; a sore mouth or tongue or a black hairy tongue have been reported. Pseudomembranous colitis has been associated with the use of most antibiotics; of the penicillins, ampicillin or amoxicillin have been implicated most frequently. The possibility of a prolonged bleeding time following oral treatment with a broad-spectrum drug like ampicillin should be borne in mild in patients receiving anticoagulants.

OVERDOSE:
Symptoms of overdose include loss of feeling in fingers and toes, pain, muscle weakness, seizures, confusion, agitation, as well as coma in severe cases.

STORAGE CONDITION:
STORE AT TEMPERATURES NOT EXCEEDING 30ºC.

AVAILABILITY:
500 mg Capsule – Foil Strip by 10's, Box of 100's

Manufactured by:
DRUGMAKER'S LABORATORIES, INC.
E & E Industrial Complex, Brgy. San Antonio San, Pedro, Laguna

Imported and Distributed by:
PHIL PHARMAWEALTH, INC.
Suite 3001, East Tower, PSE Centre, Exchange Road, Ortigas Center,
Pasig City, Philippines

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph**

Registration Number: **DRP- 5599-01**

Date of First Authorization: **August 01, 2022**

Date of revision of package insert (PI): **June 2022**