Rx CLOXACILLIN

125 mg/5 mL Powder for Oral Solution
ANTIBACTERIAL
(PENICILLIN)

FORMULATION
Each 5 mL (1 teaspoonful) contains:
CLOXACILLIN (as sodium), USP…….....……125 mg

PRODUCT DESCRIPTION
White to off-white to yellowish powder, slightly sweet with bitter taste, lemon and menthol flavored yellow solution upon reconstitution.

PHARMACODYNAMICS
Cloxacillin is bactericidal with a mode of action similar to that of benzylpenicillin, but is resistant to staphylococcal penicillinase. It is active therefore against penicillinase-producing and non-penicillinase-producing staphylococci. Its activity against streptococci such as *Streptococcus pneumoniae* and *Str. pyogenes* is less than that of benzylpenicillin, but sufficient to be useful when these organisms are present with penicillin-resistant staphylococci. Cloxacillin is virtually ineffective against *Enterococcus faecalis*.

PHARMACOKINETICS
Cloxacillin is incompletely absorbed from the gastrointestinal tract, and absorption is reduced by the presence of food in the stomach. After an oral dose of 500 mg, a peak plasma concentration of 7 to 15 micrograms/mL is attained in fasting subjects in 1 to 2 hours. Absorption is more complete when given by intra-muscular injection and peak plasma concentrations of about 15 micrograms/mL have been observed 30 minutes after a dose of 500 mg. Doubling the dose can double the plasma concentration. About 94% of cloxacillin in the circulation is bound to plasma proteins. Cloxacillin has been reported to have a plasma half-life of 0.5 to 1 hour. The half-life is prolonged in neonates.

Cloxacillin crosses the placenta and is distributed into breast milk. There is little diffusion into the CSF except when the meninges are inflamed. Therapeutic concentrations can be achieved in pleural and synovial fluids and in bone.

Cloxacillin is metabolised to a limited extent, and the unchanged drug and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion. About 35% of an oral dose is excreted in the urine and up to 10% in the bile. Cloxacillin is not removed by haemodialysis.

Plasma concentrations are enhanced by probenecid. Reduced concentrations in patients with cystic fibrosis have been attributed to both enhanced tubular secretion and enhanced nonrenal clearance of cloxacillin.

INDICATIONS
For the treatment of infections due to staphylococci resistant to benzylpenicillin including infections of the skin and soft tissues, bones and joints, respiratory tract and urinary tract; otitis media, endocarditis, septicaemia and meningitis.

DOSAGE AND MODE OF ADMINISTRATION
Usual oral doses are 250 mg to 500 mg four (4) times daily.
Children up to 2 years:
May be given 50 to 100 mg per Kg body-weight daily in divided doses every 6 hours. It should be given at least 30 minutes before meals as the presence of food in the stomach reduces absorption.
Or as prescribed by the physician.

DIRECTIONS FOR RECONSTITUTION
To make a 60 mL reconstituted solution mix thoroughly the contents with 40 mL water and shake well until the contents are dissolved. The reconstituted solution is stable for 7 days at temperatures not exceeding 30°C and 14 days when refrigerated (2°C-8°C)

PRECAUTION
Patients known to be hypersensitive to penicillin should be given an antibiotic of another class. Care is necessary if very high doses are given, especially if renal function is poor, because of the risk of neurotoxicity and also treating patients with spirochete infections, particularly syphilis. Renal, hepatic, and haemotological status should be monitored during prolonged and high-dose therapy. because of the Jarisch-Herxheimer reaction.

CONTRAINDICATIONS
Cloxacillin should not be given to patients with history of penicillin allergy or administered to neonates born of mothers hypersensitive to penicillins.
Patients allergic to cephalosporins may also be allergic to penicillins.
Cloxacillin is incompatible with aminoglycosides, tetracyclines, erythromycin and polymyxin B.

WARNING
This product contains FD & C Yellow # 5 (Tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons.

USE IN PREGNANCY
Limited number or reported cases of use in human pregnancy have shown no evidence of untoward effect. The use of Cloxacillin in pregnancy should be reserved for cases considered essential by the physician.
As with all drugs therapy with Cloxacillin should be avoided during pregnancy if possible, especially during the first trimester.
During lactation: Traces of penicillin can be determined in breast milk.

DRUG INTERACTIONS
Probenecid prolongs the half-life of Cloxacillin by competing with it for renal tubular secretion and may be used therapeutically. It may also interact with bacteriostatic antibacterials such as chloramphenicols and tetracyclines and may be incompatible in vitro with other drugs , including some other bacterials.

ADVERSE DRUG REACTION
Significant: Haematologic disorders (e.g. neutropenia, agranulocytosis, thrombocytopenia), bacterial or fungal superinfection (including pseudomembranous colitis, *Clostridium difficile*-associated diarrhoea).
Gastrointestinal disorders: Diarrhoea, nausea, vomiting, epigastric discomfort, flatulence.
General disorders and administration site conditions: Fever
Hepatobiliary disorder: Intrahepatic cholestasis.
Immune system disorders: Angioedema
Investigations: Increased AST, ALT, lactate dehydrogenase, and alkaline phosphatase.
Musculoskeletal and connective tissue disorders: Joint pains.
Nervous system disorder: Seizures, headache
Renal and urinary disorders: Acute interstitial nephritis, azotaemia
Skin and subcutaneous tissue disorders: Rash
Potentially fatal: Hypersensitivity reactions including anaphylactoid and severe cutaneous adverse reactions.

OVERDOSE AND TREATMENT
Convulsions and other signs of toxicity to the central nervous system may occur with very high doses, particularly when administered intravenously to patients with renal failure. Nephrotoxicity may occur in patients with diminished renal function. Treatment of overdosage is symptomatic and supportive.

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

AVAILABILITY
Round Boston Amber Bottle x 60 mL (Box of 1's)

SHAKE WELL BEFORE USE

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

ADR REPORTING STATEMENT
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph".
Seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER
DRP-980

FIRST AUTHORIZATION RENEWAL DATE
OCTOBER 1, 2013

DATE OF REVISION
May 2023

Manufactured by:
JM TOLMANN LABORATORIES, INC.
#95 North Zuzuarregui St., Diliman, Q. C.

170 mm

105 mm

INSERT Required size:
105mm x 170mm
Required folding:
2 Folds crosswise (facing the text)