

KLOXY®

CLOXACILLIN SODIUM PREPARATIONS

PRODUCTS:

Kloxy® Capsules : Each capsule contains Cloxacillin 250mg as Cloxacillin Sodium BP.

Kloxy® Capsules : Each capsule contains Cloxacillin 500mg as Cloxacillin Sodium BP.

Kloxy® Dry Suspension : Each 5ml measure of the reconstituted suspension contains Cloxacillin 125mg as Cloxacillin Sodium BP.

INDICATIONS:

Kloxy® or Cloxacillin is indicated in the treatment of infections caused by sensitive organisms outlined above and primarily in infections due to staphylococci resistant to benzylpenicillin such as commonly occurs in bone and joint infections, endocarditis, pneumonia, toxic shock syndrome, peritonitis often associated with continuous ambulatory peritoneal dialysis and skin infections including soft tissue infections.

DOSAGE AND ADMINISTRATION:

When administered orally, it should be given at least 30 minutes before meals to facilitate absorption.

Kloxy® or Cloxacillin may be given with other antibacterials including ampicillin so as to produce a wider spectrum of antimicrobial activity. **Kloxy®** or Cloxacillin capsules and suspension are administered orally. Usual adult doses are 500mg of cloxacillin 4 times daily by mouth. Children up to 2 years of age may be given one quarter the adult dose and those aged 2 to 10 years, one-half the adult dose. All these systemic doses may be doubled in severe infections.

ADVERSE DRUG EFFECTS AND OTHER REACTIONS:

1. As with most penicillins, the most common adverse effects are hypersensitivity reactions especially skin rashes, while nausea and diarrhoea are the more likely gastrointestinal effects to occur. Also as is common with the use of most antibiotics, pseudomembranous colitis may be experienced.
2. Patients with impaired renal function may experience the following adverse effects; (a) electrolyte disturbances; (b) prolonged bleeding time and defective platelet function; (c) haemolytic anaemia and neutropenia; (d) convulsions and other signs of CNS toxicity.
3. Patients with syphilis or other spirochaete infections may experience a Jarisch-Herxheimer reaction shortly after initiating treatment.
4. Other side effects that occur occasionally are sore throat or tongue or a black hairy tongue, neutropenia, interstitial nephritis and anaphylaxis, the extreme hypersensitivity reaction which may be fatal if it occurs.

CAUTION, PRECAUTIONS AND CONTRAINDICATIONS

1. Older patients and those receiving treatment for more than 2 weeks are at a greater risk of developing hepatitis and cholestatic jaundice.
2. Phlebitis may develop following i.v. infusion.
3. Use of isoxazolyl penicillins have in rare cases been associated with agranulocytosis and neutropenia.
4. **Kloxy®** or Cloxacillin preparations are contraindicated in patients hypersensitive to penicillin and should be given with caution to patients with known histories of allergy.
5. Anaphylactic reactions when they develop and manifesting as urticaria, hypotension or shock are best treated with parenteral adrenaline and antihistamines.

INTERACTIONS:

The possibility of a prolonged bleeding time with the use of cloxacillin in patients receiving anticoagulant therapy should be borne in mind.

Antagonism may occur with concurrent use of bacteriostatic drugs such as tetracyclines and chloramphenicol and its congeners.

PHARMACOLOGY

Pharmacodynamic Properties:

Kloxy® preparations contain Cloxacillin which is an isoxazolyl beta-lactam penicillin antibiotic with bactericidal action against Gram-positive bacteria, Gram-negative cocci, some other Gram-negative bacteria, spirochaetes and actinomycetes.

Cloxacillin exerts its antibacterial action against growing and dividing bacteria mostly by inhibiting cell-wall formation through inhibition of peptidoglycan production. Peptidoglycans hold bacterial cell-walls rigid and protect them against osmotic rupture. Cloxacillin binds to and inactivates transpeptidases on the

inner surface of the bacterial cell membranes. Transpeptidases are penicillin-binding proteins which are involved in the final cross linking stage of peptidoglycan synthesis. Other mechanisms of bacterial lysis are also involved in the bactericidal activity of cloxacillin.

ANTIMICROBIAL SPECTRUM OF ACTIVITY:

The following bacteria are sensitive to cloxacillin:

Bacillus anthracis, *Clostridium perfringens*, *Cl. tetani*, *Corynebacterium diphtheriae*, *Erysipelothrix rhusiopathiae*, *Listeria monocytogenes*, *Peptostreptococcus spp.*, Penicillinase, and non-penicillinase producing staphylococci, *Streptococcus agalactiae* (group B), *Str. pyogenes*, pneumococcus, some viridans streptococcus, meningococcus, gonococcus, *Prevotella spp.* (non-fragilis bacterioides), *Fusobacterium spp.*, *Pasturella multocida*, *Streptobacillus minus* (or minor), some strains of *Proteus mirabilis* and some strains of *Escherichia coli*. Other organisms sensitive to cloxacillin include Actinomycetes and the spirochaetes; Borrelia, Leptospira and Treponema spp.

PHARMACOKINETIC PROPERTIES:

When given orally cloxacillin is incompletely absorbed from the gastro-intestinal tract and the presence of food in the stomach or small intestines reduces absorption even further. Cloxacillin is better absorbed through the intramuscular route when a peak plasma concentration of 15 µg/ml is achieved within 30 minutes on administration of a 500mg dose. By comparison, a peak plasma concentration of 7-14 µg/ml is achieved only after 1 to 2 hours of the same oral dose given to a fasting patient. Doubling the dose can double the plasma concentration. Plasma concentration may also be enhanced by administering probenecid concomitantly.

About 94% of the cloxacillin in circulation is bound to plasma proteins and have a plasma half-life of about ½ to 1 hour. In neonates, the half-life is prolonged. Cloxacillin diffuses into the CSF only when the meninges is inflamed and also appears in breast milk, pleural fluid, synovial fluid, in bone and foetal blood circulation. Mostly the unchanged drug and the metabolites are excreted by glomerular filtration and renal tubular secretion. Of an oral dose, about 10% is excreted in bile.

LEGAL CATEGORY: Prescription Only Medicines (POM)

THERAPEUTIC CATEGORY: ATC: J01CF02 (Antibiotic - Penicillin)

STORAGE CONDITIONS:

Store in a dry place below 30°C. Protect from light. Keep all medicines out of reach of children.

On reconstitution, the suspension must be used within 7 days if stored in cool place or 14 days if stored in refrigerator (2° to 8°C)

PRESENTATIONS:

Kloxy® or Cloxacillin 250mg Capsules : Available in bulk packs of 1000's or in blister packs of 100's.

Kloxy® or Cloxacillin 500mg Capsules : Available in bulk packs of 500's or in blister packs of 100's.

Kloxy® or Cloxacillin Dry Suspension : Available as a pleasant-flavoured powder for reconstitution to 60ml/100ml with water in bottles in a unit box.

SHELF LIFE: As per product label

LAST REVIEW : August 2017

LICENCE HOLDER: LABORATORY & ALLIED LTD.



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