

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	CLOXAREN ORAL SUSPENSION (Cloxacillin 125mg/5ml Oral Suspension)
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Pack Insert:

CLOXAREN

Cloxacillin Capsules and Syrup for Reconstitution

INTRODUCTION:

Cloxaren (Cloxacillin) is semisynthetic isoxazolyl Penicillin with potent penicillinase-producing Staphylococci inhibiting property.

COMPOSITION:

CLOXAREN CAPSULES:

Each capsule contains Cloxacillin Sodium B.P equivalent to Cloxacillin 250mg.

CLOXAREN DRY SYRUP:

Each 5ml after reconstitution contains Cloxacillin Sodium USP equivalent to Cloxacillin 125mg.

MICROBIOLOGICAL ACTION:

Cloxaren (Cloxacillin) is active against a wide range of Gram-negative and Gram-positive bacteria including Streptococci species, Staphylococci (penicillin producing strains), Haemophilus influenzae, Escherichia coli, Proteus mirabilis, Salmonella species, and Neisseria species.

MECHANISM OF ACTION:

Cloxaren (Cloxacillin) acts by binding to an inactivating transpeptidases and other penicillin-binding proteins on the inner surface of the bacterial cell. This inhibits peptidoglycan production and the final cell wall cross-linking stage. This results in spheroplast formation and rapid lysis of the bacteria.

PHARMACOKINETICS:

Cloxaren (Cloxacillin sodium) is incompletely absorbed from the gastro-intestinal tract after oral administration, the absorption is further reduced by the presence of food in the stomach. After an oral dose of 500mg, a peak plasma concentration of 7 to 14µ/ml is obtained in fasting subjects in 1 to 2 hours. About 94% of Cloxacillin in the circulation is bound to the plasma proteins. Cloxacillin has been reported to have a plasma half-life of approximately 0.5 hours in healthy subjects. The half-life is prolonged in neonates. Cloxacillin diffuses across the placenta into the foetal circulation and is excreted in breast milk. Cloxacillin is metabolized to a limited extent, and the unchanged drug and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion.

INDICATIONS:

Cloxaren (Cloxacillin) is indicated in the treatment of a variety of infections due to susceptible organisms, including Respiratory tract Infections, Urinary tract Infections, Gonorrhoea, Enteric Infections, Meningitis, Septicemia, Otitis media, Biliary tract infections, and Infective Endocarditis. It may be used for the prophylaxis of staphylococcal infections during major surgical procedures, particularly in cardio thoracic and orthopedic surgery.

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DOSAGE AND ADMINISTRATION

The doses of Cloxaren will depend on the severity of the disease, and the age of the patient. The usual dose of Cloxaren is as follows:
The doses should be given 1 hour before or 2 hours after meals.
Adults: 250 to 500mg of Cloxaren every 6 hourly
Children: 50 to 100mg/kg of body weight per day in divided doses.
The dose may be doubled in severe infections and may be given with other antibiotics, especially Ampicillin, to produce a wider spectrum of activity.

CONTRAINDICATIONS:

Cloxaren (Cloxacillin) is contraindicated in patients with a history of allergic reactions to penicillins.

SIDE EFFECTS:

As with other penicillins, adverse reactions will mainly be due to penicillin hypersensitivity. These include Urticaria, fever, joint pains, Angioedema, and anaphylactic shock in hypersensitive patients. Gastro-intestinal effects like diarrhoea, nausea and heartburn may occur. A sore mouth or tongue or a black, hairy tongue due to superinfection with *Candida* may occur. Pseudomembranous colitis may occur. Bone marrow depression, granulocytopenia, prolongation of bleeding time and defective platelet function may occur in patients receiving large doses.

PRECAUTIONS:

Constant observation for signs of overgrowth with non-susceptible organisms is essential. Care is required in administration to patients with infectious mononucleosis or lymphatic leukemia or syphilis, since they are especially susceptible to erythematous rashes and Jarisch-Herxheimer reaction. Care is required if large doses are to be given to patients with impaired renal functions or congestive heart failure.

STORAGE:

CLOXAREN CAPSULES:

Store below 25°C, protected from light and moisture

CLOXAREN DRY SYRUP

Once reconstituted the suspension must be used within 7 days if stored below 25°C.

PRESENTATION

Jar of 1000 Cloxaren capsules.
Blister pack 10 x 10 Cloxaren capsules.
Cloxaren dry syrup for reconstitution.

MANUFACTURED BY

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