

# DYNA CLOXACILLIN CAPSULE

	DESCRIPTION	CONTENT
<b>DYNA CLOXACILLIN CAPSULE 250MG</b> MAL19930225AZ	CAPSULE Capsule Colour : Medium Orange/Black Capsule Size : # 2 Granules Colour : White	Each capsule contains: Cloxacillin Sodium equivalent to Cloxacillin 250 mg
<b>DYNA CLOXACILLIN CAPSULE 500MG</b> MAL07090901AZ	CAPSULE Capsule Colour : Medium Amethyst/Black Capsule Size : # 0 Granules Colour : White Marking : "DYNA" & Logo	Each capsule contains: Cloxacillin Sodium equivalent to Cloxacillin 500 mg

## PHARMACODYNAMICS:

Cloxacillin is a bactericidal antibiotic which inhibits bacterial cell wall synthesis, probably by acylation of membrane-bound transpeptidase enzymes. This prevents cross-linkage of peptidoglycan chains which is necessary for bacterial cell wall strength and rigidity. Also, cell division and growth are inhibited and lysis of susceptible bacteria frequently occurs. Rapidly dividing bacteria are most susceptible to penicillin group of antibiotics. Cloxacillin is resistant to staphylococcal penicillinase. It has an antibacterial spectrum similar to that of methicillin.

## PHARMACOKINETICS:

Cloxacillin sodium is incompletely absorbed from the gastrointestinal tract after oral administration, and absorption is further reduced by the presence of food in the stomach. After an oral dose of 500 mg, a peak plasma concentration of 7 to 14 µg per ml is obtained in fasting subjects in 1 to 2 hours. Absorption is more complete when given by intramuscular injection and peak plasma concentrations of about 15 µg per 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 are bound to 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. 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 are excreted in the urine and up to 10% in the bile. Serum concentrations are enhanced if probenecid is given concomitantly.

## INDICATION:

Infections caused by 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. It is also used for mixed streptococcal and staphylococcal infections when the staphylococci are penicillin-resistant. It is also used for the prophylaxis of staphylococcal infections during major surgical procedures, particularly in cardiothoracic and orthopaedic surgery.

## RECOMMENDED DOSE:

Adults : 250 - 500 mg every 6 hours daily.

Children : 50 - 100 mg per kg body-weight daily in divided doses.

Note: \* Patient should continue medicine for full course of treatment.

\* Take medicine on empty stomach.

\* Reduced dosage is required in patients with impaired renal function.

## ROUTE OF ADMINISTRATION:

FOR ORAL USE ONLY

## CONTRAINDICATIONS:

Patients hypersensitive to cloxacillin or a history of allergic to penicillin group of drugs.

## WARNING AND PRECAUTIONS:

Patients hypersensitive to other penicillins or cephalosporins or penicillamine may be hypersensitive to cloxacillin. If a skin rash occurs, treatment should be discontinued.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with DYNA CLOXACILLIN CAPSULE, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, DYNA CLOXACILLIN CAPSULE must be discontinued immediately and appropriate alternative therapy instituted.

## DRUG INTERACTIONS:

Probenecid impairs renal excretion. Reduces anticoagulant effect.

## PREGNANCY AND LACTATION:

Risk-benefit must be considered when given to pregnant women and during breast-feeding.

## SIDE EFFECTS/ADVERSE REACTIONS:

Side effects such as diarrhoea, nausea and heartburn may occur following administration by mouth. Sensitivity reactions may occur to patients hypersensitive to the drug. The most common side effects are allergic reaction and of these, skin rashes occur most frequently.

## SYMPTOMS AND TREATMENT OF OVERDOSE:

Overdosage may cause GIT disturbances, reversible impairment of liver function and diarrhoea. Treatment include stop antibiotic treatment, treat GIT distress by giving milk every 3 hours alternating with bismuth subcarbonate 5 g every 3 hours.

Problems of overdosage are unlikely to be encountered. Gross overdosage will produce very high urinary concentration, more so after parenteral administration. Problems are unlikely if adequate fluid intake and urinary output are maintained; however crystalluria is a possibility. More specific measures may be necessary in patients with impaired renal function; the antibiotic is removed by haemodialysis.

## PACKING/PACK SIZE(S):

**DYNA CLOXACILLIN CAPSULE 250MG** - Blister packs of 10x10's, 50x10's and 100x10's.

**DYNA CLOXACILLIN CAPSULE 500MG** - Blister packs of 10x10's and 50x10's.

**JAUHI UBAT DARIPADA KANAK-KANAK  
KEEP OUT OF REACH OF CHILDREN**

## MANUFACTURER/PRODUCT REGISTRATION HOLDER:

**DYNAPHARM (M) SDN. BHD.** 198001011897 (65683-V)

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