SPMC
CLOXACILLIN CAPSULES BP 250 mg
SPMC
CLOXACILLIN CAPSULES BP 500 mg

PRESENTATION:
Cloxacillin capsules BP 250 mg,
Pack size -1000 capsules.
Black cap printed with SPMC log and Orange body printed with letters "SPMC" circularly rectified in edible ink. Each capsule contains 250 mg of Cloxacillin.

Cloxacillin capsules BP 500 mg,
Pack size-500 capsules.
Green cap printed with "SPMC" log and Orange body printed with letters "SPMC" circularly rectified in edible ink. Each capsule contains 500 mg of Cloxacillin.

ACTION:
Cloxacillin is a bactericidal antibiotic that binds to 1 or more of the penicillin-binding proteins (PBPs) which in turn inhibit the final transpeptidation step of peptidoglycan synthesis in bacterial cell walls, thereby inhibiting cell wall synthesis. This results to bacterial lysis due to ongoing activity of cell wall autolytic enzymes (autolysins and murein hydrolases) while cell wall assembly is arrested.

INDICATIONS AND DOSE:
Bacterial infections
Adult: Staphylococcal infections resistant to benzyl penicillin: 250-500 mg 6 hourly. Dose and duration of therapy may vary depending on infecting organism, severity of infection and patient's clinical response. Max: 6,000 mg daily.
Child: ≤20 kg: 25-50 mg/kg daily in divided doses; >20 kg: Same as adult dose.

CAUTIONS:
Patient with allergies especially β-lactam allergy, asthma, history of seizure disorder. Renal impairment. Pregnancy and lactation.

SIDE EFFECTS:
Significant: Haematologic disorders (e.g. neutropenia, agranulocytosis, anaemia, thrombocytopenia), bacterial or fungal superinfection (including pseudomembranous colitis, *C. difficile*-associated diarrhoea).
Gastrointestinal disorders: Diarrhoea, loose stools, nausea, vomiting, flatulence, epigastric distress, abdominal pain, stomatitis.
General disorders and administration site conditions: Lethargy, fever.
Immune system disorders: Urticaria, serum sickness-like reaction.
Investigations: Increased serum ALT, AST, alkaline phosphatase.
Musculoskeletal and connective tissue disorders: Twitching.
Nervous system disorders: Myoclonus, seizure.
Psychiatric disorders: Confusion.
Renal and urinary disorders: Haematuria, proteinuria, renal insufficiency, renal tubular disease, interstitial nephritis.
Respiratory, thoracic and mediastinal disorders: Laryngospasm, bronchospasm, sneezing, wheezing.
Vascular disorders: Hypotension, thrombophlebitis.
Potentially
Fatal: Anaphylactoid/hypersensitivity reactions.

PREGNANCY:
Cloxacillin has been assigned to pregnancy category B. There are no controlled data in human pregnancies; however, there are no literature reports of congenital abnormalities associated with it. Cloxacillin should only be given during pregnancy when need has been clearly established. Cloxacillin should be used cautiously in pregnant women

BREAST FEEDING:
There are no data on the excretion of cloxacillin into human milk. Other penicillins are excreted into human milk in small amounts. Adverse effects in the nursing infant are unlikely.
Interruption of nursing has to be considered since Cloxacillin passes through maternal milk

MONITORING PARAMETERS:
Monitor CBC with differential prior to initiation of treatment and weekly thereafter; periodic tests for renal (e.g. urinalysis, BUN, creatinine) and hepatic function. Monitor for signs of anaphylaxis during the 1st dose.

INCOMPATIBILITY:
Incompatible with aminoglycosides.

CONTRAINDICATIONS:
Cloxacillin capsules should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients (See List of Excipients). – Cloxacillin is contraindicated for ocular administration.

ADMINISTRATION:
Should be taken on an empty stomach. Take 1 hour before or 2 hour after meals. Delayed absorption in the presence of food.

IMPORTANT SAFETY INFORMATION:
Observe for signs and symptoms of anaphylaxis during 1st dose. Monitor CBC with differential (prior to initiating therapy and weekly thereafter), periodic BUN, creatinine, hepatic function
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DRUG INTERACTION:
Increased serum concentration with probenecid. May increase serum concentration of methotrexate. May interfere with the anticoagulant effect of vitamin K antagonists (e.g. warfarin). Tetracycline may diminish the effect of cloxacillin.

FOOD INTERACTION:
Food reduces cloxacillin absorption.

LAB INTERFERENCE:
May cause false-positive test results for urine and serum proteins, uric acid and urinary steroids. May interfere with urinary glucose tests using cupric sulfate (Benedict's solution, Clinitest).

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

OVERDOSE:
Overdosage with oral cloxacillin is unlikely to cause serious reactions if renal function is normal. Gastrointestinal effects such as nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically.

STORAGE:
Keep tightly closed in a cool & dry place. Store below 25°C in the original package in order to protect from moisture & Light.

Keep all medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha,
Kandawala Estate,
Ratmalana, Sri Lanka.