DAWACLOX®
Injection/Capsules/Syrup

Composition:
Each vial contains Cloxacillin as Sodium B.P equivalent to Cloxacillin 250 or 500 mg.
Each capsule contains Cloxacillin as Sodium B.P equivalent to Cloxacillin 250 mg.
Each 5ml of the reconstituted syrup contains Cloxacillin as Sodium B.P equivalent to Cloxacillin 125 mg.

List of excipients:
Dry Syrup: Vanilla powder, sunset yellow colour, sodium benzoate, sodium citrate, sodium CMC, sodium chloride and sucrose.
Capsules: Magnesium stearate and hard gelatin capsule.

Pharmacology:
Cloxacillin is a narrow spectrum antibiotic of the group of isoxazolylpenicillins; it is not inactivated by staphylococcal beta-lactamases.
Cloxacillin, by its action on the synthesis of the bacterial wall, exerts a bactericidal effect on streptococci, staphylococci, including the beta-lactamase-producing strains, clostridia and neisseria. It is not active against methicillin-resistant staphylococci. The Group A beta-haemolytic streptococci are less sensitive to the isoxazolyl penicillins than to penicillin G or penicillin V.

Pharmacokinetics:
Absorption: Absorbed rapidly but incompletely (37-60%) from the GIT tract; it's relatively acid stable. Food may decrease both rate and extent of absorption.
Distribution: Cloxacillin is widely distributed. CSF penetration is poor but enhanced in meningeal inflammation.
Cloxacillin crosses the placenta, and is 90- 96% protein bound.
Metabolism: Cloxacillin is only partially metabolized.
Excretion: Cloxacillin is excreted in urine by renal tubular secretion and glomerular filtration; also excreted in breast milk.
Elimination $T_{1/2}$ in adults is ½ to 1 hour, extended minimally to $2_{1/2}$ hours in patients with renal impairment.

Indications:
Cloxacillin is indicated for the treatment of infections due to Gram-positive organisms, including infections caused by β-lactamase producing staphylococci.
Typical indications include:
Skin and Soft Tissue Infections e.g. boils abscesses, carbuncles, furunculosis, cellulitis, infected wounds, infected burns, protection of skin grafts, and impetigo. Infected skin Conditions: e.g. ulcer, eczema and acne.
Respiratory Tract Infections: Pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, quinsy, otitis media and externa.
Other infections caused by cloxacillin-sensitive organisms such as osteomyelitis, enteritis, endocarditis, urinary tract infection, meningitis, septicemia.

Contraindications:
Patients known to be hypersensitive to penicillins should be given an antibacterial of another class.
Dosage and directions for use:
Syrup and capsules for oral administration only.
It should be given at least 30 minutes before meals.
Usual oral doses are 250mg to 500 mg four times daily. Children may be given 50mg to 100 mg/kg daily in divided doses every 6 hours.
Cloxacillin sodium has also been given by intramuscular or slow intravenous injection or infusion. Other routes of administration have included intra-articular and intrapleural injection.

Precautions:
Desensitization may be attempted if treatment with penicillin is considered essential. Penicillins should be given with caution to patients with a history of allergy, especially to drugs. Care is necessary if very high doses of penicillins are given, especially if renal function is poor, because of the risk of neurotoxicity.
The intrathecal route should be avoided. Renal, hepatic, and haematological status should be monitored during prolonged and high-dose therapy.
Because of the Jarisch-Herxheimer reaction, care is also necessary when treating patients with spirochaete infections, particularly syphilis.
Skin contact with penicillins should be avoided since sensitisation may occur. Penicillin therapy changes the normal bacterial flora and can lead to supra-infection with penicillin-resistant organisms including *Clostridium difficile* or *Candida,* particularly with prolonged use.

Use in pregnancy and lactation:
Pregnancy: Cloxacillin has been assigned to pregnancy category B. There are no controlled data in human pregnancies; however, there is no literature reports of congenital abnormalities associated with it. Cloxacillin should only be given during pregnancy when need has been clearly established.
Lactation: Drug is excreted in breast-milk and therefore should not be used.

Side-effects:
CNS: Lethargy, hallucinations, seizures, anxiety, confusion, agitation, depression, dizziness and fatigue.
GI: Nausea, vomiting, epigastric distress, diarrhea, enterocolitis, pseudo membranous colitis, black 'hairy' tongue, transient elevations in liver function study results and abdominal pain.
Hematologic: eosinophilia, anemia, thrombocytopenia, leucopenia, hemolytic anemia, agranulocytosis.
Hepatic: Intrahepatic cholestasis.
Others: Hypersensitivity reactions (rash, urticaria, hills, fever, sneezing, wheezing, anaphylaxis), overgrowth of non-susceptible organisms.

Interactions:
Drug-drug:
The possibility of a prolonged bleeding time following oral treatment with a broad-spectrum drug like Cloxacillin should be borne in mind in patients receiving anticoagulants. Cloxacillin sodium has been reported to be incompatible with aminoglycosides and a number of other antimicrobials.
Probenecid increases serum levels of cloxacillin. It maybe used fro this purpose.
Drug-food:
Foods decrease drug absorption. Advise taking drug on an empty stomach. Fruit juices and carbonated beverages may inactivate the drug. Don't give together.

Over dosage and treatment:
Symptoms of over dosage are as per side-effects. Treatment is symptomatic and supportive.

Presentation:
Vials: dry powder for reconstitution in 10ml and 20 ml bottles.
Dry powder for syrup: dry powder for reconstitution in 60ml and 100ml bottles
Capsules: HDPE jars with 1000 capsules, Carton pack with 10x10 blisters.

Shelf life:
Capsules: 3 years from the date of manufacture.
Dry syrup: 3 years from the date of manufacture, to be used within 7 days once reconstituted.

Storage:
Store in a dry place, below 30°C, protected from direct sunlight
Dry syrup: Once reconstituted, store the bottle tightly closed in a cool dry place, below 30°C, preferably in a refrigerator. Do not freeze.
Keep all medicines out of reach of children.

Manufactured by:

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