CLOXACAP CAPSULE

VICLO37-var (MY)4

DESCRIPTION

Cloxacap 250 mg Capsule
Orange opaque and grey opaque capsule with "HD" printed on one end and "CX 250" on the other end of the capsule.

Cloxacap 500 mg Capsule
Orange opaque and black opaque capsule with “HD” printed on one end of the capsule and “CX500” on the other end.

COMPOSITION

Cloxacap 250 mg Capsule
Cloxacillin Sodium equivalent to Cloxacillin 250 mg/capsule.

Cloxacap 500 mg Capsule
Cloxacillin Sodium equivalent to Cloxacillin 500 mg/capsule.

ACTIONS AND PHARMACOLOGY

Cloxacillin, a bactericidal antibiotic, inhibits bacterial cell wall synthesis by preventing 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.

Oral absorption is reduced by food. It is extensively bound to plasma proteins and excretion is via renal and biliary systems.

INDICATIONS

For treatment of:

- Infections caused by penicillinase-producing staphylococci
- Respiratory tract infections
- Skin and soft-tissue infections
- Disseminated infections caused by pneumococci, group A beta-hemolytic streptococci and penicillin G-resistant and penicillin G-sensitive staphylococci

CONTRAINDICATIONS

Avoid in patients known to be hypersensitive to penicillins.

WARNINGS AND PRECAUTIONS

Risk-benefit should be considered when the following medical problems exist:

- General history of allergy such as asthma, eczema, hay fever and hives.
- History of bleeding disorders.
- History of gastrointestinal disease especially ulcerative colitis, regional enteritis or antibiotic-associated colitis.
- Infectious mononucleosis.
- Caution in patients with known history of allergy and in severe renal function impairment.
- 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 Cloxacap, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Cloxacap must be discontinued immediately and appropriate alternative therapy instituted.

SIDE/ADVERSE EFFECTS

- Hematologic reactions, specifically neutropenia (sore throat and fever) especially with high doses and platelet dysfunction (unusual bleeding or bruising).
- Pseudomembranous colitis (severe abdominal or stomach cramps and pain; abdominal tenderness, watery and severe diarmoea, which may also be bloody; fever)
- Interstitial nephritis (fever, rash, possibly decreased urine output, proteinuria, hematuria).
- The most common adverse effect is a hypersensitivity reaction such as diarrhoea, nausea and vomiting.

PREGNANCY AND LACTATION

Safety for use in pregnancy and lactation has not been established.

Cloxacillin crosses the placenta and is distributed into the breastmilk.

OVERDOSAGE

Clinical features:
Anorexia, nausea, vomiting, abdominal discomfort and diarrhoea.

Treat overdosage by emesis or gastric lavage, if appropriate; and treat gastrointestinal distress, if any, by giving milk every 3 hours alternating with bismuth subcarbonate 5 g every 3 hours.

DRUG INTERACTIONS

- Aspirin, sulphamethoxypyridazine and sulphathiazole inhibits the serum binding of cloxacillin *in vitro* and *in vivo.*
- Incompatible with aminoglycoside, tetracyclines and other antimicrobial agents including erythromycin and polymyxin B-sulphate.

DOSAGE AND ADMINISTRATION

Cloxacillin should not be used orally for the initial treatment of severe life-threatening infections, but may be used as a follow-up therapy after parenteral penicillinase-resistant penicillin therapy.

Adult dose
Oral, 250 to 500 mg every six hours; or as directed.

Paediatric dose
Infants and children up to 20 kg of body weight:
Oral 12.5 to 25 mg per kg of body weight every six hours; or as directed.

Children 20 kg of body weight and over - See adult dose.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage: Store below 25°C. Protect from light and moisture.

Presentation/Packing:
Capsule 250 mg blister of 10 x 10's.
Capsule 500 mg blister of 10 x 10's
(Not all presentations are available locally.)

Product Registration Holder (Malaysia) / Product Owner / Manufactured by: HOVID Berhad
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