150x300mm

For the use of Registered Medical Practitioner of Hospital or a Laboratory only

Cloxacillin Sodium Capsules USP 125/250/500mg and
Cloxacillin Sodium for Oral Solution USP 125mg

COMPOSITION

1.Each hard gelatin capsule contains:
Cloxacillin Sodium USP
Eq. to Cloxacillin 125/250/500 mg
Excipients q.s.
Approved colours used in empty capsule shells
2. Each 5ml (after reconstitution) contains:
Cloxacillin Sodium USP
Eq. to Cloxacillin 125mg
Excipients q.s.
Colour: Approved colours used

CLINICAL PHARMACOLOGY

Mechanism of action

Cloxacillin is semi-synthetic penicillin, resistant to penicillinase, and is therefore active against penicillinase-producing staphylococci. Cloxacillin is in general less effective against organisms susceptible to benzylpenicillin, such as streptococci, pneumococci and non-penicillinase producing staphylococci, and is not useful against gram-negative bacteria.

Pharmacokinetic Properties:

Cloxacillin is stable in an acid medium and is approximately 50% absorbed orally. After an oral dose of 500mg cloxacillin, a peak serum level of about 8 micrograms/mL is reached in about 1 hour. The serum level after i.m. cloxacillin is approximately twice that obtained when the same dose is given orally to fasting adults. Food in the stomach or small intestine reduces absorption and peak serum levels are approximately 50% those obtained after fasting. As with other penicillins, concurrent administration of probenecid enhances the serum concentration. Once absorbed, approximately 94% are bound to plasma proteins. After oral administration, roughly 20% of the dose is excreted in the urine, together with one or more active metabolites as yet unidentified. The half life of elimination is about 30 minutes.

INDICATION AND USAGE

Cloxacillin is indicated for the treatment of infections due to penicillinase-producing staphylococci that are resistant to benzylpenicillin. It is used against gram-positive staphylococcus aureus in:

- skin and soft tissue infections, e.g. abscesses, cellulitis.
- pneumonia
- endocarditis
- osteomyelitis

CONTRA-INDICATION

- Cloxacillin should not be given to patients with a history of penicillin allergy or administered to neonates born of mothers hypersensitive to penicillin.
- Patients allergic to cephalosporins may also be allergic to penicillins.
- Cloxacillin is incompatible with aminoglycosides, tetracyclines, erythromycin and polymyxin B.

DRUG INTERACTIONS

Probenecid

As with other penicillins, concurrent administration of probenecid enhances the serum concentration of Cloxacillin.

WARNINGS AND PRECAUTIONS

Hematologic:

During long-term therapy, renal, hepatic and hematopoietic functions should be checked periodically.

Hepatic:

During long-term therapy, renal, hepatic and hematopoietic functions should be checked periodically.

Immune:

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patients receiving penicillin or cephalosporin therapy. These reactions are more apt to occur in individuals with a history or sensitivity to multiple allergens. Careful inquiry should be made concerning previous hypersensitivity to reactions to penicillins, cephalosporins or other allergens. If allergic or anaphylactic reactions occur, discontinue treatment and administer the usual agents, e.g. antihistamines, pressor amines, corticosteroids.

Neurologic:

The passage of any penicillin from blood into brain is facilitated by inflamed meninges and during cardiopulmonary bypass. In the presence of such factors, particularly in renal failure when high serum concentration can be attained, CNS adverse effects including myoclonia, convulsive seizures and depressed consciousness can be expected. Although this complication has not been reported with Cloxacillin, it should be anticipated.

Sensitivity/Resistance:

Candidiasis and other super-infections may occur, especially in debilitated and malnourished patients, or those with low resistance to infection due to corticosteroids, immunosuppressors or irradiation. If super-infection occurs, institute appropriate measures.

Renal:

During long-term therapy, renal, hepatic and hematopoietic functions should be checked periodically.

SIDE EFFECTS

Sensitivity reactions may include skin rashes, angioedema, bronchospasm, serum sickness and anaphylaxis, and sometimes death within minutes. Treatment with adrenaline, corticosteroids, aminophylline or antihistamines may be necessary. A generalised sensitivity reaction can develop within a few hours or weeks of commencing treatment, including urticaria, fever, joint pains and eosinophilia. Other allergic reactions include exfoliative dermatitis and maculopapular rashes, interstitial nephritis and vasculitis. Haemolytic anaemia, leucopenia, prolonged bleeding time and defective platelet function can occur.Oral administration may produce diarrhoea, heartburn and nausea, and hepatitis and cholestatic jaundice have been reported. A sore mouth or tongue, and a black hairy tongue have also been reported. Supra-infection with *C. albicans*, other fungi or organisms resistant to Cloxacillin may occur.Care should be taken when administering high doses of Cloxacillin especially to patients with impaired renal function as there is a risk of neuro-toxicity and congestive heart failure. Disturbance of electrolyte balance may occur following administration of large doses. Increases in liver enzyme values have been reported.
Renal and haematological systems should be monitored during prolonged and high dose therapy; patients with syphilis may exhibit the Jarish-Herxheimer reaction and should also therefore be monitored.
A skin test for sensitivity may be used to determine those patients most likely to develop allergic reactions to penicillins.

DOSAGE & MODE OF ADMINISTRATION

Posology

Adults: Mild to moderate infections: 250 to 500 mg every 6 hours. It should be given 1 to 2 hours before meals as the presence of food in the stomach and small intestine reduces absorption. Maintain therapy for a minimum of 5 days. Larger doses may be required for very severe infections. A daily dose of 6 g should not be exceeded.

Children: Up to 5 kg (11 lb) body weight: 250 mg/day. Over 5 kg (11 lb) up to approximately 40 kg (85 lb) body weight: 50 mg/kg/day. Total daily dosage must be divided into 4 doses, 1 dose given every 6 hours.

In infections associated with streptococcus pyogenes, treatment should be continued for at least 10 days to reduce the risk of glomerulonephritis or rheumatic fever.

Method of administration

Cloxacillin Sodium Capsules is for oral use.

Therapy can be started parenterally according to the dosing recommendations of the intravenous formulation and continued with an oral preparation.

- Swallow with water without opening capsule.
- Take bottle until all powder flows freely. Add approximately 1/3th of the total amount of water for reconstitution and shake vigorously to wet powder. Add remainder of the water and again shake vigorously.

PREGNANCY AND LACTATION

Pregnancy
Safety in pregnancy has not yet been established.

STORAGE : Store in a dry & dark place below 30°C, protected from moisture.

KEEP THE MEDICINE OUT OF REACH & SIGHT OF CHILDREN

PRESENTATION : 10 strips of 10 capsules are packed in a Unit carton along with leaflet.

SCOTT-EDIL

MANUFACTURED BY
Scott-Edil Advance Research
Laboratories & Education Ltd.
Hill Top Industrial Area, Bhatoli Kalan,
Baddi, Dist. Solan - 173205 (HP) INDIA

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