175 mm

This Patient information leaflet is applicable for

CLOXACILLIN ORAL SOLUTION USP 125 mg/5 ml
CLOXACILLIN ORAL SOLUTION USP 250 mg/5 ml
CLOXACILLIN SODIUM CAPSULES USP 250 mg
CLOXACILLIN SODIUM CAPSULES USP 500 mg

Read this entire leaflet carefully before you start using this medicine:
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

COMPOSITION:
Solution: When reconstituted as directed, each 5 ml of the solution contains cloxacillin sodium USP equivalent to 125 mg or 250 mg of cloxacillin.
colour: Approved colour used.
Capsules: Each capsule contains cloxacillin sodium USP equivalent to 250 mg or 500 mg cloxacillin. Approved colours used in empty hard gelatin capsules shells.

PHARMACOLOGICAL CLASSIFICATION:
Penicillin Antibiotic.

PHARMACOLOGICAL ACTION:
Cloxacillin is a 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.

INDICATIONS:
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-INDICATIONS:
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.

WARNINGS:
Use with caution in patients with a known history of allergy to penicillins. When administered to a patient with penicillin sensitivity anaphylactic shock may occur. Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis. Due to the variability in intestinal absorption, oral administration is not a suitable substitute for the parenteral treatment of serious infections.

DOSAGE AND DIRECTIONS FOR USE:
Solution: Slowly add purified water slightly below the mark & shake vigorously. Adjust the volume up to the mark by adding more water. if necessary.
This make 60 ml or 100 ml. solution.
Adults: 500 mg (20 ml solution) six hourly, administered one hour before meals.
Children: (2-10 yrs)250 mg (10 ml solution) six hourly, administered one hour before meals.

CAPSULES:
Adults: One 500 mg capsule six hourly, administered one hour before meals.
Children: (2-10 yrs)One 250 mg capsule six hourly, administered one hour before meals.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Sensitivity reactions may include skin rashes, angioedema, bronchospasm, serum sickness and anaphylaxis, and sometimes death within minutes. Treatment with adrenaline, corticosteroids, aminophyllin 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. Haemolyticanaemia, 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Convulsions and other signs of toxicity to the central nervous system may occur with very high doses, particularly when administered intravenously to patients with renal failure. Nephrotoxicity may occur in patients with diminished renal function. Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:
Solution: Slightly pinkish free-flowing powder for the preparation of a flavoured syrup.
Capsules 250 mg: Size 2 hard gelatin capsule with a orange body and black cap, printed with Cloxa 250.
Capsules 500 mg: Size 0 hard gelatin capsule with a white body and red cap, printed with Cloxa 500.

PRESENTATION:
Solution: Bottles of 60 ml & 100 ml with purified water.
Capsules: Securitainers 100, 500 or 1000 capsules HDPE containers & Blister Packs of
10 x 10, 100 x 10 Capsules.

STORAGE:
Store below 25°C and dry place.
Protect from light.

MEDICINES INFORMATION:
Should you need any information about this product, please write to us at medicines.info@milanlabs.com

Keep all medicines out of reach of children.

Manufactured in India by:
MILÂN LABORATORIES (INDIA) PVT. LTD.
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