## 1.4 Product Information

### 1.4.1. Summary of Product Characteristics (Product Data Sheet)

**1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT**
CLOXACILLIN CAPSULES USP 250mg

**2. QUALITATIVE & QUANTITATIVE COMPOSITION**

| Constituent | Quantity/ capsule(mg) |
|---|---|
| Cloxacillin Sodium equivalent to Cloxacillin | 273.570<br>250.000 |
| Magnesium Stearate | 4.000 |
| Lactose | 8.430 |
| Purified Talc | 4.000 |
| Size '2' E.H.G. Capsules, Black/orange | 1 capsule |

**3. PHARMACEUTICAL FORM**
Oral Capsules

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**
Used to treat infections caused by penicillinase-producing staphylococci, including pneumococci, group A beta-hemolytic streptococci, and penicillin G-sensitive and penicillin G-resistant staphylococci.

**4.2 Posology and method of administration**
Route of administration Oral.
Adults
250-500mg every 6 hours.
Children
25mg per pound of body weight, in 4 divided doses, daily.

**4.3 Contraindications**
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.

**4.4 Special warnings and special precautions for use**
A skin test for sensitivity may be used to determine those patients most likely to develop allergic reactions to penicillins.

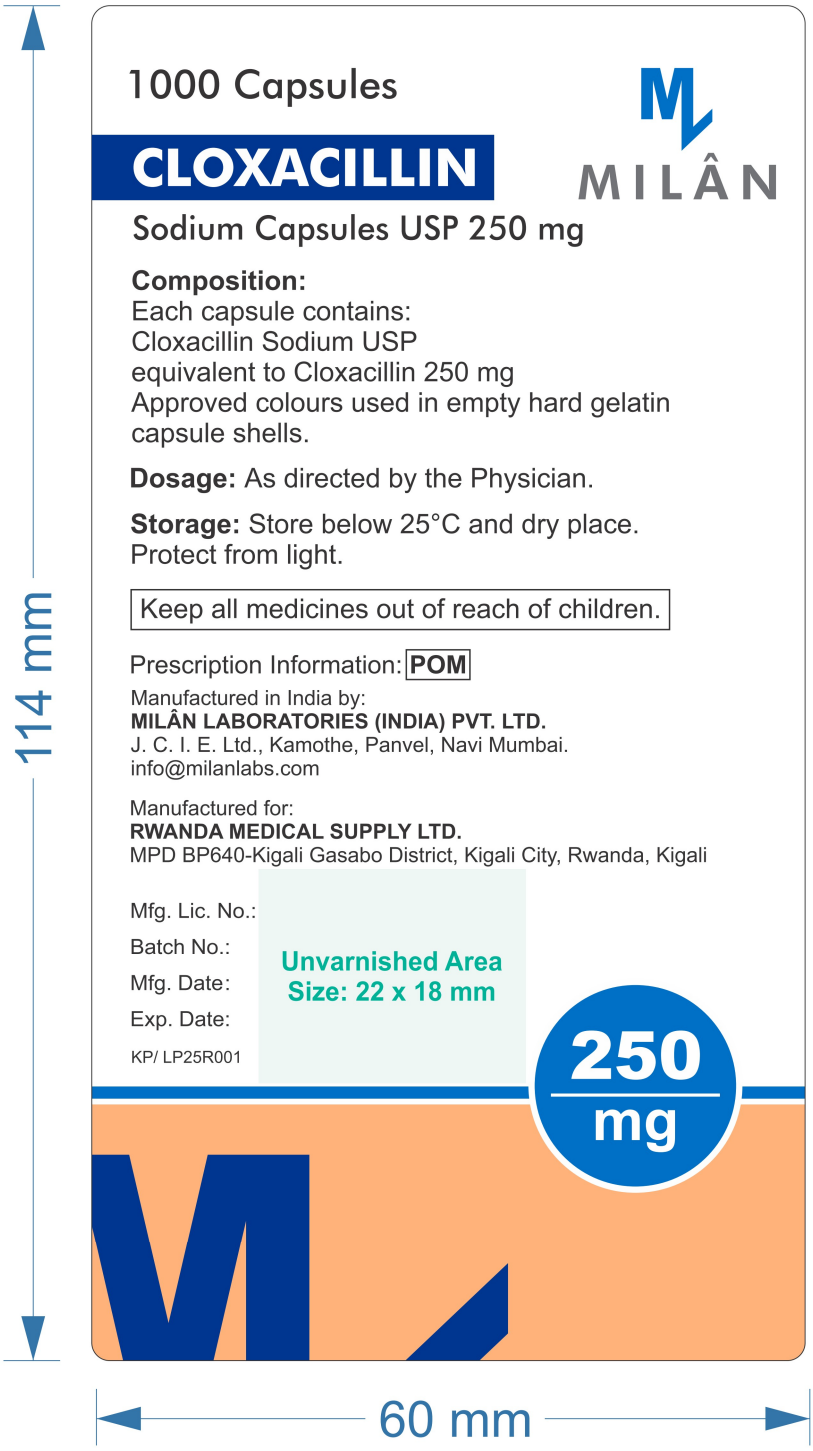
Supra-infection with C. albicans, other fungi or organisms resistant to cloxacillin may occur. Care should be taken when administering high doses of cloxacillin especially to patients with impaired renal function as there is a risk of neuro-toxicity and congestive heart failure. Disturbance of electrolyte 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.
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.

**4.5 Interaction with other FPPs and other forms of interaction**
Fusidic Acid: May diminish the therapeutic effect of Penicillins.
Methotrexate: Penicillins may decrease the excretion of Methotrexate.
Mycophenolate: Penicillins may decrease serum concentrations of the active metabolite(s) of Mycophenolate. This effect appears to be the result of impaired enterohepatic recirculation.
Tetracycline Derivatives: May diminish the therapeutic effect of Penicillins.
Uricosuric Agents: May decrease the excretion of Penicillins.

**4.6 Pregnancy and lactation**
If you are pregnant or planning to become pregnant, inform your physician before taking Cloxacillin.
Nursing mothers should switch to bottle-feed while taking Cloxacillin.

**4.7 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.

**4.8 Undesirable effects**
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.


1000 Capsules
CLOXACILLIN
MILÂN
Sodium Capsules USP 250 mg
Composition:
Each capsule contains:
Cloxacillin Sodium USP
equivalent to Cloxacillin 250 mg
Approved colours used in empty hard gelatin capsule shells.
Dosage: As directed by the Physician.
Storage: Store below 25°C and dry place.
Protect from light.
Keep all medicines out of reach of children.
Prescription Information: POM
Manufactured in India by:
MILÂN LABORATORIES (INDIA) PVT. LTD.
J. C. I. E. Ltd., Kamothe, Panvel, Navi Mumbai.
info@milanlabs.com
Manufactured for:
RWANDA MEDICAL SUPPLY LTD.
MPD BP640-Kigali Gasabo District, Kigali City, Rwanda, Kigali
Mfg. Lic. No.:
Batch No.:
Mfg. Date:
Exp. Date:
KP/ LP25R001
Unvarnished Area
Size: 22 x 18 mm
250
mg
114 mm
60 mm

**4.9 Overdose**
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.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic Properties**
ATC-Code: J01CF02
Pharmacotherapeutic group: Belongs to a class of beta-lactamase resistant penicillins. Used in the treatment of systemic infections.
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.

**5.2 Pharmacokinetic properties**
Cloxacillin is incompletely absorbed from the gastrointestinal tract after oral administration, and absorption is further reduced by the presence of food in the stomach. After an oral dose of 500 mg, a peak plasma concentration of 7 to 14 micrograms per mL is attained in fasting subjects in 1 to 2 hours. Absorption is more complete when given by intramuscular injection and peak plasma concentrations of about 15 micrograms per mL have been observed 30 minutes after a dose of 500 mg. Doubling the dose can double the plasma concentration. About 94% of Cloxacillin in the circulation is bound to plasma proteins. Cloxacillin has been reported to have a plasma half-life of 0.5 to 1 hour. The half-life is prolonged in neonates.
Cloxacillin crosses the placenta and is distributed into breast milk. There is little diffusion into the CSF except when the meninges are inflamed. Therapeutic concentrations can be achieved in pleural and synovial fluids and in bone.
Cloxacillin is metabolised to a limited extent, and the unchanged drug and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion. About 35% of an oral dose is excreted in the urine and up to 10% in the bile. Cloxacillin is not removed by haemodialysis. Plasma concentrations are enhanced if probenecid is given concomitantly.

**5.3 PRECLINICAL SAFETY DATA**
Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**
Magnesium stearate, Lactose, Purified Talc, EHG Capsules.

**6.2 Incompatibilities**
Not applicable

**6.3 Shelf life**
24 months

**6.4 Special precautions for storage**
Store below 25°C, dry place. Protect from light.

**6.5 Nature and contents of container**
Alu-PVDC Blister pack of 10x10 Capsules in a carton & HDPE container of 1000 capsules in P.P. bag.

**6.6 Instructions for use and handling**
Keep out of reach of children.

**7. MARKETING AUTHORISATION HOLDER**
Milan Laboratories (India) Pvt. Ltd.
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Road No. 9, Opposite MIDC Office,
Wagle Estate, Thane -400604
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E-mail: mllabs@vsnl.com

**8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS**
To be allocated

**9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION**
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**10. DATE OF REVISION OF THE TEXT**
Not Applicable