

**MILAN LABORATORIES (INDIA) PVT. LTD.**

**CLOXACILLIN CAPSULES USP 250mg**



**Patient Information leaflet (PIL)**

**1. Product Name:** CLOXACILLIN CAPSULES USP 250mg

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

**In this leaflet:**

**1. What Cloxacillin Capsules are and what they are used for**

**2. Before you take Cloxacillin Capsules**

**3. How to take Cloxacillin Capsules**

**4. Possible side effects**

**5. How to store Cloxacillin Capsules**

**6. Further information**

**a) What Cloxacillin Capsules are and what they are used for**

Cloxacillin Capsules are 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.

**b) Before you take Cloxacillin Capsules**

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.

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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.

**c) How to take Cloxacillin Capsules**

Route of administration Oral.

Adults

250-500mg every 6 hours.

Children

25mg per pound of body weight, in 4 divided doses, daily.

**d) Possible side 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. 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.

**e) How to store Cloxacillin Capsules**

Do not store above 30°C. Protect from light

“Keep all medicines out of reach of children”

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Do not use these medicines after the expiry date which is stated on the blister/label after EXP.  
The expiry date refers to the last day of that month.

**f) Further information**

**What Cloxacillin Capsules contains**

- The active substances are of cloxacillin as cloxacillin sodium.

Each capsule contains:

Cloxacillin sodium USP

Equivalent to Cloxacillin 250mg

- The other ingredients are:

Magnesium stearate, Lactose, Purified Talc, EHG Capsules

**What Cloxacillin Capsules looks like and contents of the pack**

Black/orange coloured size “2” hard gelatin capsule printed “CLOXA 250” with white edible ink containing off white granular powder.

PRESENTATION:

**Blister Pack:**

Alu-PVC Blister of 10 x10 Tablets packed in a carton along with the pack Insert.

**Bulk Pack:**

1000 Tablets in P.P. Bag packed in a HDPE Container.

**Marketing Authorisation Holder and Manufacturing Site Addresses**

MILAN LABORATORIES (INDIA) PVT. LTD.

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