1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CLOXIN 250 mg CAPSULES

Cloxacillin

Sugar free

CLOXIN 500 mg CAPSULES

Cloxacillin

Sugar free

Read all of this leaflet carefully before you start taking CLOXIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CLOXIN has been prescribed for you personally and you should not share CLOXIN with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CLOXIN is and what it is used for
2. What you need to know before you take CLOXIN
3. How to take CLOXIN
4. Possible side effects
5. How to store CLOXIN
6. Contents of the pack and other information

1. What CLOXIN is and what it is used for

CLOXIN belongs to a group of antibiotics called penicillins. CLOXIN is used to treat bacterial infections including:

- Skin and soft tissue infections, e.g. abscesses (boils), cellulitis (inflammation of tissue below the skin).
- Pneumonia (inflammation of the lungs with congestion).
- Endocarditis (inflammation of the lining of the heart and its valves).
- Osteomyelitis (infection of the bone).

2. What you need to know before you take CLOXIN

Do not take CLOXIN:

- If you are hypersensitive (allergic) to cloxacillin or to any of the excipients of CLOXIN (listed in section 6).
- If you have a known history of allergy to penicillin.
- If the baby is born from a mother hypersensitive to penicillin.
- If you are also allergic to cephalosporins (also a group of antibiotics) as you may also be allergic to penicillins.
- If you are also taking other antibiotics called aminoglycosides, tetracyclines, erythromycin and polymyxin B.

Warnings and precautions

Take special care with CLOXIN:

- If you are hypersensitive to CLOXIN as this hypersensitivity could progress to Kounis syndrome, a serious allergic reaction that can result in a heart attack. You should not take CLOXIN if you are hypersensitive to CLOXIN (see Do not take CLOXIN).

- If you experience a rash, fever or joint pain hours or weeks after starting treatment with CLOXIN, you should see your doctor as this could be an allergic reaction.
- If you develop a fungal infection as this can occur while taking CLOXIN.
- If you have serious infections as you should receive medicine directly in your veins (parenteral), and not orally.
- If you have problems with your kidneys (especially if you are taking high doses).
- If you will be taking high doses of CLOXIN for a long time, because you will need to be monitored.
- If you have liver problems, as increases in liver enzyme values have been reported.
- If you have syphilis as taking CLOXIN could cause a reaction called Jarisch-Herxheimer which could be dangerous. Symptoms of this reaction can include fever, chills, headache and reactions at the site of the lesion. Your doctor will need to monitor you.
- If you have porphyria, as taking CLOXIN could cause acute attacks.
- If you have cystic fibrosis.
- If you are on haemodialysis, as CLOXIN is not removed from the body by haemodialysis.

If you are not sure if you are sensitive to penicillins, then your doctor can do a skin test to determine if you might be allergic.

Other medicines and CLOXIN

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Aminoglycosides, tetracyclines, erythromycin or polymyxin B (other types of antibiotics), as they should not be taken together with CLOXIN (see Do not take CLOXIN).
- Chloramphenicol (an antibiotic) as it may interact with CLOXIN.
- Medicine to prevent your blood from clotting (anticoagulants) as there is a possibility of prolonged bleeding time.
- Oral contraceptives (medicine to prevent you from falling pregnant) as CLOXIN may decrease the efficacy.
- Methotrexate (used to suppress the immune system) as its effects may be enhanced.
- Probenecid (medicine used in gout) as higher concentrations of CLOXIN may occur.

CLOXIN with food and drink

CLOXIN should be taken one hour before meals.

Pregnancy and breastfeeding

The safety of CLOXIN during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking CLOXIN.

Driving and using machines

It is not always possible to predict to what extent CLOXIN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which CLOXIN affects you (see Possible side-effects).

3. How to take CLOXIN

Do not share medicines prescribed for you with any other person.

Always take CLOXIN exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

One 500 mg capsule six hourly, administered one hour before meals.

Children 2 to 10 years: One 250 mg capsule six hourly, administered one hour before meals.

Your doctor will tell you how long your treatment with CLOXIN will last. Do not stop treatment early. If you have the impression that the effect of CLOXIN is too strong or too weak, tell your doctor or pharmacist.

If you take more CLOXIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take CLOXIN

If you have missed a dose of CLOXIN, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take several doses, contact your doctor without delay.

If you stop taking CLOXIN

You should not stop taking CLOXIN without talking to your healthcare provider first even if you feel better.

4. Possible side effects

CLOXIN can have side effects.

Not all side effects reported for CLOXIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLOXIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking CLOXIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, eyes, lips and mouth, tongue or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLOXIN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Inflammation of the liver (hepatitis) with symptoms such as dark urine and pale or clay-coloured stools, fatigue, yellowing of the skin or eyes, loss of appetite and nausea and vomiting,
- a condition in which the flow of bile from the liver stops or slows (cholestatic jaundice) with symptoms such as abdominal pain, yellowing of the skin or eyes, loss of appetite and bloating,
- too few white blood cells (leukopenia, neutropenia), with symptoms such as fever, mouth sores, sore throat, or increased susceptibility to infections,
- increased number of a certain type of white blood cells in the blood (eosinophilia) with symptoms such as weight loss, fevers, night sweats, fatigue,
- a blood disorder that makes your red blood cells break down or die faster than your body can replace them with new blood cells (haemolytic anaemia) with symptoms such as abnormal paleness or lack of colour of the skin, weakness, dizziness and a feeling that you cannot handle physical activity,
- a condition where the body muscles contract and relax rapidly and repeatedly, resulting in uncontrolled shaking (convulsions). Fits (convulsions) occur especially with high doses in children or in patients with renal failure,
- a syndrome that affects the arteries (Kounis syndrome) caused by an allergic reaction or a strong immune reaction to a medicine or other substance with symptoms such as chest pain, shortness of breath, nausea, vomiting, and light-headedness,
- a skin disorder characterised by bull's-eye-shaped lesions (erythema multiforme, this could even appear 15 days after stopping treatment),
- a rare immune-mediated blistering skin disease (linear IgA disease) appearing as an itchy rash with small blisters, often arranged in clusters or rings,

- inflammation of the blood vessels (vasculitis) with symptoms such as fever, fatigue, weight loss and muscle and joint pain,
- a severe inflammation of the inner lining of the large intestine (pseudomembranous colitis) with symptoms such as watery diarrhoea, stomach cramps, pain or tenderness, fever and pus or mucus in the stool,
- a syndrome that is characterized by skin rash, joint stiffness, joint pain, facial and extremity swelling, and fever (serum sickness),
- a severe inflammation of the entire skin surface (exfoliative dermatitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- A sore mouth or tongue, transient diarrhoea, nausea.

Less frequent side effects:

- Prolonged bleeding time or excessive bruising or bleeding (defective platelet function),
- a kidney disorder in which the spaces between the kidney tubules become swollen (interstitial nephritis),
- heartburn.

Frequency unknown:

- Skin rash (urticaria), fever, joint pains,
- a black hairy tongue, itchy anus,
- increase in liver enzyme values as seen on blood tests,

- symptoms of other bacterial or fungal infections not susceptible to CLOXIN, inform your doctor as you will require other treatment.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of CLOXIN.

5. How to store CLOXIN

Store all medicines out of reach of children.

Store at or below 25 °C. Keep container tightly closed.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLOXIN contains

Each CLOXIN 250 mg CAPSULE contains 250 mg cloxacillin as cloxacillin sodium.

Each CLOXIN 500 mg CAPSULE contains 500 mg cloxacillin as cloxacillin sodium.

Sugar free.

The other ingredients are:
Erythrosine (C.I. 45430), gelatin, iron oxide black, magnesium stearate, potassium hydroxide, propylene glycol, shellac, starch maize, sunset yellow (C.I. 15985), titanium dioxide (C.I. 77891).

What CLOXIN looks like and the contents of the pack

CLOXIN 250 mg CAPSULES:
A hard gelatin capsule (Size 2) with an opaque orange cap and an opaque white body, containing a white powder. “Cloxin 250” printed on the body and cap in black ink.

100 capsules are packed in a white opaque polypropylene container with a white opaque low density polyethylene cap.

100 capsules are packed in a high density polyethylene container with a white high density polyethylene cap with an aluminium seal.

CLOXIN 500 mg CAPSULES:
A hard gelatin capsule (Size 0 EL) with an opaque orange cap and an opaque white body, containing a white powder. “Cloxin 500” printed on the body and cap in black ink.

100 capsules are packed in a white opaque polypropylene container with a white opaque linear low density polyethylene cap.

100 capsules are packed in a high density polyethylene container with a white polypropylene cap with induction liner within the cap.

Not all packs are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/+27 11 239 6200

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Registration numbers

CLOXIN 250 mg CAPSULES: N/20.1.2/90

CLOXIN 500 mg CAPSULES: N/20.1.2/91

Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia:	NS2
CLOXIN 250 mg CAPSULES:	90/20.1.2/00861
CLOXIN 500 mg CAPSULES:	90/20.1.2/00862