

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

CLOXACILLIN SODIUM FOR ORAL SOLUTION USP 125MG/5ML

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Each 5ml of Reconstituted Solution Contains:

Cloxacillin Sodium USP

Equivalent to Cloxacillin 125mg

Sodium benzoate contains 0.60mg

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Powder for oral solution

Light pink coloured powder with a pleasant flavor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cloxacillin Sodium for Oral Solution is indicated for the treatment of all staphylococcal infections. It is of particular value in treating mixed Gram-positive infections, e.g. infected burns where the presence of a penicillinase-producing staphylococci may inactivate other penicillins before they can exert any effect on the otherwise sensitive organisms. It is indicated in the following:

Pneumonia	Tonsillitis and pharyngitis
Osteomyelitis	Infected burns
Wound infections	Acute and sub-acute endocarditis
Boils and carbuncles	Staphylococcal enteritis
Abscesses and cellulitis	Staphylococcal meningitis
Otitis media	Staphylococcal urinary tract infection

4.2 Posology and method of administration

Route of administration Oral.

To reconstitute the solution, add water as per direction given on label and shake well to dissolve.

The preparation is administered orally with a measuring cup.

Adults: 500mg (20ml Solution) six hourly, administered one hour before meal.

Children: 250mg (10ml syrup) six hourly, administered one hour before meals.

4.3 Contraindications

Cloxacillin Sodium for Oral Solution 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

Warning

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

Safety for use in pregnancy has not been established.

Precaution

Candidiasis and other superinfections may occur, especially in debilitated and malnourished patients, or those with low resistance to infection due to corticosteroids, immunosuppressive agents or irradiation. If superinfection occurs, institute appropriate measures.

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

Experience in premature and newborn infants is limited. Cautious administration of the drug to such patients and frequent evaluation of organ system function is recommended.

The passage of any penicillin from the 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 concentrations can be attained, central nervous system adverse effects including myclonia, convulsive seizures and depressed consciousness can be expected. Although this complication has not been reported with cloxacillin, it should be anticipated.

4.5 Interaction with other medicinal products and other forms of interaction

There may be an interaction between cloxacillin and any of the following:

- aminoglycosides (e.g., gentamicin, tobramycin)
- birth control pills
- methotrexate
- tetracyclines (e.g., minocycline, doxycycline)
- typhoid vaccine

- warfarin

If you are taking any of these medications, speak with your doctor or pharmacist. Depending on your specific circumstances, your doctor may want you to:

- stop taking one of the medications,
- change one of the medications to another,
- change how you are taking one or both of the medications, or
- leave everything as is.

An interaction between two medications does not always mean that you must stop taking one of them. Speak to your doctor about how any drug interactions are being managed or should be managed.

Medications other than those listed above may interact with this medication. Tell your doctor or prescriber about all prescription, over-the-counter (non-prescription), and herbal medications you are taking. Also tell them about any supplements you take. Since caffeine, alcohol, the nicotine from cigarettes, or street drugs can affect the action of many medications, you should let your prescriber know if you use them.

4.6 Pregnancy and lactation

Cloxacillin has been assigned to pregnancy category B. There are no controlled data in human pregnancies; however, there are no literature reports of congenital abnormalities associated with it. Cloxacillin should only be given during pregnancy when need has been clearly established. Cloxacillin should be used cautiously in pregnant women.

Lactation

There are no data on the excretion of cloxacillin into human milk. Other penicillins are excreted into human milk in small amounts. Adverse effects in the nursing infant are unlikely. Interruption of nursing has to be considered since Cloxacillin passes through maternal milk.

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

Gastrointestinal disturbances, such as nausea, vomiting, epigastric discomfort, flatulence and loose stools, have been noted in some patients. Rarely, mild leukopenia has occurred. Mildly elevated SGOT levels (less than 100 units) have been reported in a few patients for whom pre-

therapeutic determinations were not made. Fever, anaphylaxis and allergic reactions (rash, urticaria) including wheezing and sneezing, have occasionally been encountered.

Eosinophilia, with or without overt allergic manifestations, has been noted in some patients during therapy. Thrombophlebitis has occurred occasionally I.V. therapy.

4.9 Overdose

When penicillin reaches a certain (as yet undetermined) concentration in the cerebrospinal fluid, neurotoxic symptoms may occur consisting of myoclonia, convulsive seizures, and depressed consciousness. Unless administration of the drug is stopped or its dosage reduced, the syndrome may progress to coma and death. Penicillin does not normally cross the blood-brain barrier to any substantial extent, but when massive doses are used (several grams a day) in the presence of inflamed meninges and/or impaired renal function, or in elderly patients, the drug may cause the above-mentioned toxic reactions. No antidote is required.

Stop administration temporarily - promote excretion (dialysis, etc.)

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 Has been approved to relieve symptoms and also for the treatment and maintenance of Bloodstream infection due to methicillin-susceptible *S. aureus*, Endocarditis due to methicillin-susceptible staphylococci, Osteomyelitis due to methicillin-susceptible *S. aureus*, Localized purulent skin lesions, impetigo, Arthritis(septic), Methicillin-sensitive *Staphylococcus aureus*, Endocarditis, Osteomyelitis, Pneumonia, MSSA, Pneumonia, nosocomial, Septicemia and Skin, and soft tissues.

5.2 Pharmacokinetic properties

Cloxacillin is well-absorbed after oral administration, with peak plasma concentrations reached within 1-2 hours. Its bioavailability is approximately 35-55%, and it is not affected by food. Cloxacillin is widely distributed in body fluids and tissues, including bone, skin, lungs, and pleural fluid. It has a low protein binding of approximately 85%. Cloxacillin is not metabolized in the liver and is eliminated unchanged in the urine. Cloxacillin is primarily eliminated by the kidneys, with a half-life of approximately 30 minutes in patients with normal renal function. In patients with renal impairment, the elimination half-life may be prolonged, and dosage adjustments may be necessary.

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

Sodium benzoate, Sodium citrate, Saccharin sodium, Citric acid, Sucrose, Essence Peppermint dry powder, Colour Erythromycin supra.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a dry place below 25°C. Protect from light.

6.5 Nature and contents of container

100ml Amber colored glass bottle.

6.6 Instructions for use and handling

Keep out of reach of children.

7. MARKETING AUTHORISATION HOLDER

Milan Laboratories (India) Pvt. Ltd.

303 & 304, Odyssey IT park,

Road No. 9, Opposite MIDC Office,

Wagle Estate, Thane -400604

India

E-mail: info@milanlabs.com

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

06640/08047/REN/2021

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

19-10-2021

10. DATE OF REVISION OF THE TEXT

July 2023