SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

CLOXACILLIN CAPSULES USP 500mg

2. QUALITATIVE & QUANTITATIVE COMPOSITION

Each capsule contains:

Cloxacillin Sodium USP

Equivalent to Cloxacillin 500mg

Lactose contains 16.860mg

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Oral Capsules

Red/White coloured size "0" hard gelatin capsules printed "CLOXA 500" with black edible ink containing off-whitecoloured granular powder.

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.

It should be given l to 2 hours before meals as the presence of food in the stomach and small intestine reduces absorption. Maintain therapy for a minimum of 5 days.

Larger doses may be required for very severe infections.

A daily dose of 6 g should not be exceeded.

Children

(2-10 yrs) One 250mg capsule six hourly, administered one hour before meals.

Up to 5 kg (11 lb) body weight: 250 mg/day.

Over 5 kg (11 lb) up to approximately 40 kg (85 lb) body weight: 50 mg/kg/day. Total daily dosage must be divided into 4 doses, 1 dose given every 6 hours.

4.3 Contraindications

A history of allergic reactions to penicillin or cephalosporins.

4.4 Special warnings and special precautions for use

Warning

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patientsreceiving penicillin therapy. These reactions are more apt to occur in individuals with a history ofsensitivity to multiple allergens. Careful inquiry should be made concerning previous hypersensitivityreactions 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, orthose with low resistance to infection due to corticosteroids, immunosuppressive agents or irradiation. Ifsuperinfection 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 suchpatients 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 duringcardiopulmonary bypass. In the presence of such factors, particularly in renal failure when high serumconcentrations can be attained, central nervous system adverse effects including myclonia, convulsiveseizures and depressed consciousness can be expected. Although this complication has not been reportedwith 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 pregnancycategory B. There are no controlled data inhuman pregnancies; however, there are noliterature reports of congenital abnormalitiesassociated with it. Cloxacillin should only begiven during pregnancy when need has beenclearly established. Cloxacillin should be usedcautiously in pregnant women.

Lactation

There are no data on the excretion of cloxacillininto human milk. Other penicillins are excretedinto human milk in small amounts. Adverseeffects in the nursing infant are unlikely. Interruption of nursing has to be consideredsince 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 loosestools, have been noted in some patients. Rarely, mild leukopenia has occurred. Mildly elevatedSGOT levels (less than 100 units) have been reported in a few patients for whom pre-therapeuticdeterminations were not made. Fever, anaphylaxis and allergic reactions (rash, urticaria) includingwheezing and sneezing, have occasionally been encountered.

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

4.9 Overdose

When penicillin reaches a certain (as yet undetermined) concentration in the cerebrospinalfluid, neurotoxic symptoms may occur consisting of myoclonia, convulsive seizures, anddepressed consciousness. Unless administration of the drug is stopped or its dosage reduced, thesyndrome may progress to coma and death. Penicillin does not normally cross the blood-brainbarrier to any substantial extent, but when massive doses are used (several grams a day) in thepresence of inflamed meninges and/or impaired renal function, or in elderly patients, the drugmay 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 andmaintenance of Bloodstream infection due to methicillin-susceptible S. aureus,Endocarditis due to methicillin-susceptible staphylococci, Osteomyelitis due tomethicillin-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

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

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

08255/08294/REN/2021

9.DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

22-12-2022

10. DATE OF REVISION OF THE TEXT

July 2023