Summary of Product Characteristics

1. Name of the medicinal product :

Generic Name: Ampicillin and Cloxacillin Capsules

2. Qualitative and Quantitative composition:

Composition:

Each Hard Gelatin Capsule Contains: Ampicillin Trihydrate BP EQ To
Ampicillin …….250 mg
Cloxacillin sodium BP
Eq. To Cloxacillin…….250 mg
Excipients……Q.S

UNIT FORMULA

Sr. No.	Raw Material	Reference	Mg/cap.	Overages %	Std. Qty. (kg) 606000 caps
1.	Cloxacillin Sodium	BP	272.5 mg = 250 mg	-	165.135
2.	Ampicillin Trihydrate	BP	287.5 mg = 250 mg	-	174.225
3.	Colloidal silicon dioxide	BP	4.00	-	2.424
4.	Purified Talc	BP	16.00	-	9.696
5.	Magnesium Stearate	BP	8.00	-	4.848

6.	EHG Capsule black/purple size “0”	IH	1 NOS.	1%	606000

3. Pharmaceutical Form: Oral (Capsule)

4. Clinical Particulars:

4.1 Therapeutic indications

It is indicated for the treatment of the following infections including mixed Gram-positive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections:
Surgery: Post-operative wound infections, post-operative pulmonary infections.
Respiratory infections: Bronchopneumonia, acute exacerbations of chronic bronchitis.
Obstetrics: Puerperal fever.
Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections.

4.2 Posology and method of administration

Adult: 500 mg to 1.0 gm every 6 hrs. or more often depending on the severity of infection or as directed by the Physician.

Children: 1 month -2 yrs.: ¼ the adult dose. 2 yrs-10 yrs. ½ the adult dose.

Administer the dose ½ to 1 hr. before meals.

Method of administration For oral use.

4.3 Contraindications

Ampicillin and Cloxacillin capsule should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients (See List of Excipients). – Ampicillin and Cloxacillin is contraindicated for ocular administration.

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Before initiating therapy with Ampicillin and Cloxacillin, careful inquiry should be made concerning previous

hypersensitivity reactions to beta-lactams.

Cross-sensitivity between penicillins and cephalosporins is well documented.

Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals should be discontinued and the appropriate alternative therapy instituted. All adverse reactions should be treated symptomatically.

Ampicillin and Cloxacillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin. Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

Pseudomembranous colitis has been reported with the use of antibiotics and may range in severity from mild to life-threatening. Therefore, it is important to consider its diagnosis in patients who develop diarrhoea during or after antibiotic use. If prolonged or significant diarrhoea occurs or the patient experiences abdominal cramps, treatment should be discontinued immediately and the patient investigated further.

Dosage should be adjusted in patients with renal impairment

Cloxacillin can displace bilirubin from protein-binding sites. Normal caution should therefore be exercised in the treatment of jaundiced neonates.

The sodium content of the formulation must be included in the daily allowance of patients on sodium restricted diets.

4.5 Interaction with other medicinal products and other forms of interaction

Probenecid decreases the renal tubular excretion of Ampicillin and Cloxacillin. Concurrent use with Ampicillin and Cloxacillin may result in increased and prolonged blood levels of Ampicillin and Cloxacillin.

In common with other antibiotics, Ampicillin and Cloxacillin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. Bacteriostatic drugs may interfere with the bactericidal action of Ampicillin and Cloxacillin. Concurrent administration of allopurinol during treatment with Ampicillin and Cloxacillin can increase the likelihood of allergic skin reactions.

4.6 Fertility, pregnancy and lactation

Cloxacillin should be used cautiously in pregnant women.

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

Adverse reactions are listed below by system organ class and frequency.

Blood and lymphatic system disorders

Very rare: Hemolytic anemia, leucopenia, thrombocytopenia, and agranulocytosis.

Immune system disorders

Very rare: Anaphylaxis and other hypersensitivity reactions

Skin disorders and interstitial nephritis have been reported as hypersensitivity reactions.

(See also Skin and subcutaneous tissue disorders and Renal and urinary disorders).

If any hypersensitivity reaction occurs, the treatment should be discontinued.

Nervous system disorders

Very rare: Myoclonus and convulsions

Gastrointestinal disorders

Common: Diarrhoea and nausea

Uncommon: Vomiting

Very rare: Pseudomembranous colitis (See Warnings and Precautions) and haemorrhagic colitis

Hepatobiliary disorders

Very rare: Hepatitis and cholestatic jaundice. A moderate and transient increase in transaminases Skin and subcutaneous tissue disorders Common: Skin rash, urticaria, and pruritus.

The incidence of skin rash, pruritus, and urticaria is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin.

Very rare: Bullous reactions (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis), exfoliative dermatitis and purpura

Skin disorders have also been reported as hypersensitivity reactions (See Immune system disorders).

Renal and urinary disorders

Very rare: Interstitial nephritis

Interstitial nephritis has also been reported as a hypersensitivity reaction (See also Immune system disorders).

Section 4.8 Reporting of adverse effects

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board,Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Over dosage with oral ampicillin and cloxacillin is unlikely to cause serious reactions if renal function is normal. Gastrointestinal effects such as nausea, vomiting, and diarrhoea may be evident. These symptoms should be treated symptomatically.

5. Pharmacological properties

5.1 Pharmacodynamic properties Pharmacotherapeutic Group:

Cloxacillin is a narrow-spectrum antibiotic of the isoxazolyl penicillin group; it is not inactivated by staphylococcal betalactamases. Ampicillin is a broad-spectrum antibiotic of the aminopenicillin group; it is not resistant to beta-lactamases.

Both ampicillin and cloxacillin are bactericidal antibiotics and act by interfering with the formation of new bacterial cell wall by dividing organisms.

The prevalence of acquired resistance is geographically variable and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

Ampicillin and cloxacillin susceptibility rates are higher than ampicillin rates due to the cloxacillin activity against β-lactamase producing staphylococci. Methicillin-susceptible Staphylococcus aureus (MSSA) and methicillin-susceptible coagulase-negative staphylococcus (MSCoNS) are commonly susceptible to Ampicillin and cloxacillin. MRSA and MRCoNS are resistant to Ampicillin and cloxacillin. For all other indicated bacterial species, the susceptibility of Ampicillin and cloxacillin is similar to ampicillin including limited activity against Gram-negative organisms.

5.2 Pharmacokinetic properties

Absorption

Both ampicillin and cloxacillin are stable in the gastric environment resulting in good absorption. Neither component of the combination of ampicillin and cloxacillin interferes with the absorption or excretion of the other. The total quantity absorbed by the oral route represents 50% (cloxacillin) and 40% (ampicillin) of the quantity administered. 8 The presence of food in

the stomach may depress oral absorption and Ampicillin and cloxacillin should therefore be taken 0.5 to 1 hour before meals.

Distribution

Ampicillin and cloxacillin diffuses well into most tissues and body fluids including, among others, bronchial secretions, sinuses, saliva, cerebrospinal fluid (variable percentage depending on the degree of meningeal inflammation), bile, serous membranes and middle ear. Crossing the meningeal barrier: ampicillin and cloxacillin diffuses in only small proportion into the cerebrospinal fluid of subjects whose meninges are not inflamed. Crossing into breast milk: Ampicillin and cloxacillin is excreted in small quantities in breast milk. Plasma half-life for cloxacillin is 0.5 to 1 hour and 1 to 1.5 hour for ampicillin. Protein binding: the serum protein binding proportion is approximately 94% for cloxacillin and 18% for ampicillin.

Metabolism

In normal subjects approximately 20% (cloxacillin) and 40% (ampicillin) of the dose administered is metabolised.

Excretion

Ampicillin and cloxacillin is eliminated mainly through the kidney. Approximately 30% of the dose administered orally and over 60% of the ampicillin dose administered parenterally is eliminated in active form in the urine within 24 hours. The equivalent percentages for cloxacillin are approximately 20% and 30% respectively. A small proportion (10%) of the dose administered is excreted in bile.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Colloidal silicon dioxide

Purified Talc

Magnesium Stearate

EHG Capsule black/purple size “0”

6.2 Incompatibilities Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30 º C. Protect from light. Do not freeze.

6.5 Nature and contents of container

10 x 10 Capsules packed in Alu PVC blister packed in printed carton with insert.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder:

Medico Remedies Pvt Ltd

8. Marketing Authorization Number:

9. Date of first Authorization /renewal of the authorization: --

10. Date of revision of text:

31/03/2026