1. NAME OF THE MEDICINAL PRODUCT
AC Clox Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

- Ampicillin (as trihydrate): 250 mg
- Cloxacillin (as sodium salt): 250 mg

3. PHARMACEUTICAL FORM
Capsule.
Description: Purple and black hard gelatin capsules containing a white to off-white powder.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications

AC Clox Capsule is indicated for the treatment of infections caused by susceptible organisms, including:

- Respiratory tract infections (e.g., bronchitis, pneumonia)
- Skin and soft tissue infections (e.g., cellulitis, abscesses)
- Bone and joint infections (e.g., osteomyelitis)
- Urinary tract infections
- Bacterial septicemia and endocarditis

4.2 Posology and Method of Administration
Adults and children over 12 years:
One capsule (250 mg Ampicillin + 250 mg Cloxacillin) every 6 hours (four times daily).

Children under 12 years:
Dosage should be determined by the physician based on body weight and clinical condition.

Route of Administration: Oral. Capsules should be swallowed whole with water, preferably one hour before or two hours after meals.

4.3 Contraindications

- Hypersensitivity to penicillins, cephalosporins, or any other components of the formulation.
- History of anaphylactic reactions to beta-lactam antibiotics.

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with renal impairment; dosage adjustment may be required.
- Monitor for signs of anaphylaxis during the first dose.
- Prolonged use may result in overgrowth of non-susceptible organisms, including fungi.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Probenecid: Prolongs the serum concentration of Ampicillin.
- Oral contraceptives: Efficacy may be reduced; alternative contraceptive measures are recommended.
- Anticoagulants: May enhance anticoagulant effect; monitor INR/PT.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Use only if clearly needed; animal studies do not indicate direct or indirect harmful effects.
- Lactation: Trace amounts of Ampicillin and Cloxacillin are excreted in breast milk. Monitor breastfeeding infants for allergic reactions or gastrointestinal effects.

4.7 Effects on Ability to Drive and Use Machines

No adverse effects on the ability to drive or use machinery have been observed.

4.8 Undesirable Effects

Common adverse effects include:

- Gastrointestinal disturbances: nausea, vomiting, diarrhea
- Allergic reactions: rash, urticaria, anaphylaxis (rare)
- Hepatic dysfunction: transient elevations in liver enzymes

Report any adverse effects to AC Drugs Limited via the provided contact details.

4.9 Overdose

Symptoms: Nausea, vomiting, diarrhea, and electrolyte imbalance.
Management: Supportive care, gastric lavage, and activated charcoal if indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Mechanism of Action:
Ampicillin and Cloxacillin are beta-lactam antibiotics. Ampicillin exhibits broad-spectrum activity against Gram-positive and Gram-negative bacteria, while Cloxacillin is effective against penicillinase-producing staphylococci.

5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed after oral administration; reduced with food intake.
- Distribution: Widely distributed in body tissues and fluids; crosses the placenta and appears in breast milk.
- Metabolism and Excretion: Primarily excreted unchanged in urine; half-life ~1 hour.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Magnesium stearate

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 Years

6.4 Special Precautions for Storage

Store below 30°C in a dry place, away from direct sunlight. Keep out of reach of children.

6.5 Nature and Contents of Container

AC Clox Capsule is available in blister packs of 10 capsules.

7. MARKETING AUTHORIZATION HOLDER

AC Drugs Limited
Plot C5/C6 Old Airport Road,
Emene, Enugu State, Nigeria.

8. MARKETING AUTHORIZATION NUMBER

[To be provided upon regulatory approval]

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

[To be specified]

10. DATE OF REVISION OF THE TEXT

December 2024