1. NAME OF THE MEDICINAL PRODUCT
AC Clox Powder for Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5mL of the reconstituted suspension contains:

- Ampicillin (as trihydrate): 125 mg
- Cloxacillin (as sodium salt): 125 mg

3. PHARMACEUTICAL FORM
Powder for Oral Suspension.
Description: A white to off-white powder that reconstitutes into a palatable suspension with a fruity flavor.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
AC Clox Powder for Suspension is indicated for the treatment of infections caused by susceptible organisms, including:

- Upper and lower respiratory tract infections (e.g., pharyngitis, bronchitis, pneumonia)
- Skin and soft tissue infections (e.g., impetigo, cellulitis)
- Bone and joint infections
- Urinary tract infections
- Otitis media

4.2 Posology and Method of Administration
Children (by weight):

- Under 10 kg: 125 mg Ampicillin + 125 mg Cloxacillin (5mL) every 6 hours.
- Over 10 kg: 10-15 mg/kg of body weight every 6 hours (or as directed by the physician).

Adults:
Not commonly used in adults. If necessary, dose as per the weight-based regimen.

Route of Administration: Oral. Shake well before use. Administer one hour before or two hours after meals to ensure better absorption.

4.3 Contraindications

- Known hypersensitivity to penicillins or cephalosporins.
- Patients with a history of anaphylactic reactions to beta-lactam antibiotics.
- Severe renal impairment without dosage adjustment.

4.4 Special Warnings and Precautions for Use

- Monitor for hypersensitivity reactions, particularly in patients with a history of allergies.
- Use cautiously in patients with renal or hepatic impairment.
- Prolonged therapy may lead to superinfection with resistant organisms, including fungi.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Probenecid: Inhibits renal excretion, prolonging the half-life of Ampicillin.
- Oral contraceptives: May reduce efficacy; additional contraceptive measures are recommended.
- Anticoagulants: Enhanced risk of bleeding; monitor coagulation parameters.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: No known teratogenic effects, but use only if clearly indicated.
- Lactation: Excreted in small amounts in breast milk; monitor breastfed infants for potential allergic reactions or gastrointestinal upset.

4.7 Effects on Ability to Drive and Use Machines
Not applicable; no known effects on the ability to drive or use machinery.

4.8 Undesirable Effects
Common adverse reactions:

- Gastrointestinal: Nausea, diarrhea, and vomiting.
- Allergic Reactions: Rash, urticaria, pruritus, and anaphylaxis (rare).
- Hepatic: Elevated liver enzymes (transient).
- Hematological: Eosinophilia, leukopenia (rare).

4.9 Overdose
Symptoms of overdose include nausea, vomiting, and diarrhea.
Management: Symptomatic treatment with attention to fluid and electrolyte balance. Activated charcoal may be considered.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic Properties
Mechanism of Action:
Ampicillin and Cloxacillin are beta-lactam antibiotics. Ampicillin has broad-spectrum activity against Gram-positive and Gram-negative bacteria, while Cloxacillin is effective against penicillinase-producing staphylococci.

5.2 Pharmacokinetic Properties

- Absorption: Both antibiotics are rapidly absorbed after oral administration; food may reduce absorption.
- Distribution: Widely distributed in body tissues and fluids, including pleural and peritoneal fluids.
- Excretion: Excreted primarily unchanged in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Talc
- Na CMC
- Na Citrate
- Na Benzoate
- Mg Stearate
- Vanilla
- Citric acid
- Sugar
- Starch

6.2 Incompatibilities

None known.

6.3 Shelf Life

- 3 Years

6.4 Special Precautions for Storage

- Store the dry powder below 30°C in a dry place.
- Keep out of the reach of children.
- After reconstitution, refrigerate and discard any unused suspension after 7 days.

6.5 Nature and Contents of Container

AC Clox Powder is supplied in amber-colored glass or plastic bottles containing powder sufficient to prepare 60mL of suspension.

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