

## **1. Name of the Medicinal Product**

A.C Clox Drop

Ampicillin 60 mg/0.6 ml

Cloxacillin 30 mg/0.6 ml

## **2. Qualitative and Quantitative Composition**

Each 0.6 ml of reconstituted suspension contains:

- Ampicillin (as trihydrate): 60 mg
- Cloxacillin (as sodium salt): 30 mg

Excipients: For a full list of excipients, see section 6.1.

## **3. Pharmaceutical Form**

Dry powder for suspension.

A white to off-white powder that, upon reconstitution with water, forms a homogenous suspension.

## **4. Clinical Particulars**

### **4.1 Therapeutic Indications**

- Treatment of bacterial infections caused by susceptible organisms, including respiratory tract infections, skin and soft tissue infections, and urinary tract infections.
- Specifically indicated for mixed infections requiring coverage for both gram-positive and gram-negative bacteria.

### **4.2 Posology and Method of Administration**

- Adults and Children over 12 years: As directed by the physician.
- Children (below 12 years): Dosage depends on weight and severity of infection. Typically, 25-50 mg/kg/day in divided doses.

### **Method of Administration:**

Oral. Reconstitute the powder by adding water to the mark indicated on the bottle (15 ml) and shake well.

### **4.3 Contraindications**

- Hypersensitivity to penicillins or any of the excipients.
- Severe renal impairment (without dose adjustment).

### **4.4 Special Warnings and Precautions for Use**

- Use with caution in patients with a history of allergic reactions to beta-lactams.
- Monitor renal, hepatic, and hematologic function during prolonged therapy.
- Discontinue if severe allergic reaction or diarrhea occurs.

#### **4.5 Interaction with Other Medicinal Products**

- Probenecid prolongs the excretion of penicillins.
- May reduce efficacy of oral contraceptives.
- Avoid concurrent use with bacteriostatic antibiotics such as tetracyclines.

#### **4.6 Fertility, Pregnancy, and Lactation**

- Pregnancy: Ampicillin and cloxacillin can be used during pregnancy if clinically justified.
- Lactation: Small amounts are excreted in breast milk. Use caution.

#### **4.7 Effects on Ability to Drive and Use Machines**

None known.

#### **4.8 Undesirable Effects**

- Common: Nausea, vomiting, diarrhea, and rash.
- Rare: Anaphylaxis, Stevens-Johnson Syndrome, hemolytic anemia.

#### **4.9 Overdose**

Symptoms: Nausea, vomiting, and diarrhea.

Management: Symptomatic and supportive. Hemodialysis may help in severe cases.

### **5. Pharmacological Properties**

#### **5.1 Pharmacodynamic Properties**

- Mechanism of Action: Ampicillin and cloxacillin inhibit bacterial cell wall synthesis by binding to penicillin-binding proteins, resulting in bacterial lysis.
- Spectrum of Activity: Covers gram-positive (e.g., *Staphylococcus aureus*) and gram-negative bacteria (e.g., *Escherichia coli*).

#### **5.2 Pharmacokinetic Properties**

- Absorption: Rapid absorption after oral administration.
- Distribution: Widely distributed in body tissues and fluids.
- Excretion: Primarily excreted unchanged in urine.

#### **5.3 Preclinical Safety Data**

No additional preclinical data of relevance.

### **6. Pharmaceutical Particulars**

#### **6.1 List of Excipients**

- Na benzoate
- Na CMC
- Vanilla
- Talc
- EDTA
- Na Citrate
- Citric Acid
- Mg Stearate
- Starch

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf Life**

- 3 Years

## **6.4 Special Precautions for Storage**

- Store the dry powder below 25°C.
- Keep the reconstituted suspension refrigerated at 2–8°C.

## **6.5 Nature and Contents of Container**

1 bottle per packet

## **6.6 Special Precautions for Disposal**

No special requirements. Dispose of in accordance with local regulations.

## **7. Marketing Authorization Holder**

AC Drugs Limited

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

## **8. Marketing Authorization Number(s)**

[To be assigned by the regulatory authority]

## **9. Date of First Authorization / Renewal of the Authorization**

[To be completed following approval]

## **10. Date of Revision of the Text**

December 2024