1. Name of the Medicinal Product
AC Mox Capsule 500 mg

2. Qualitative and Quantitative Composition
Each capsule contains:
Active Ingredient: Amoxicillin (as Amoxicillin Trihydrate) – 500 mg

3. Pharmaceutical Form
Hard capsule.
Yellow and black-colored capsule containing white to off-white powder.

4. Clinical Particulars
4.1 Therapeutic Indications
AC Mox Capsule is indicated for the treatment of infections caused by susceptible strains of microorganisms, including:

- Respiratory tract infections (e.g., sinusitis, bronchitis, pneumonia).
- Urinary tract infections.
- Skin and soft tissue infections.
- Dental abscesses.
- Gonorrhea.

4.2 Posology and Method of Administration
Adults and adolescents (≥12 years):

- Standard dose: 500 mg every 8 hours.
- Severe infections: 750 mg to 1 g every 8 hours, as prescribed.

Children (<12 years):

- Not recommended for this strength; use appropriate pediatric formulations.

Renal impairment:

- Dose adjustments may be necessary for patients with reduced renal function.

Administration:

- Capsules should be swallowed whole with water, before or after meals.

4.3 Contraindications

- Hypersensitivity to amoxicillin, penicillins, or any of the excipients.
- History of severe hypersensitivity reactions (e.g., anaphylaxis) to beta-lactam antibiotics (e.g., cephalosporins).

4.4 Special Warnings and Precautions for Use

- Monitor for allergic reactions, particularly in patients with a history of penicillin allergy.
- Use with caution in patients with renal impairment.
- Risk of superinfections (e.g., Candida) with prolonged use.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Anticoagulants: Increased risk of bleeding with warfarin or other oral anticoagulants.
- Allopurinol: Increased risk of rash.
- Methotrexate: Increased toxicity due to reduced excretion of methotrexate.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Can be used during pregnancy if the potential benefit outweighs the risk.
- Lactation: Small amounts of amoxicillin are excreted in breast milk. Monitor for potential effects on the infant (e.g., diarrhea or fungal infections).

4.7 Effects on Ability to Drive and Use Machines

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

4.8 Undesirable Effects

Common side effects include:

- Gastrointestinal: Nausea, diarrhea, abdominal pain.
- Skin: Rash, urticaria.
- Rare: Anaphylaxis, Stevens-Johnson syndrome, angioedema.

4.9 Overdose

Symptoms of overdose may include nausea, vomiting, diarrhea, and electrolyte imbalance. Management includes symptomatic treatment and monitoring.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: Penicillins with extended spectrum (ATC code: J01CA04). Amoxicillin inhibits bacterial cell wall synthesis by binding to penicillin-binding proteins (PBPs).

5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed after oral administration.
- Distribution: Widely distributed in body tissues and fluids; crosses the placenta.
- Metabolism: Minimal hepatic metabolism.
- Excretion: Primarily excreted via the kidneys.

5.3 Preclinical Safety Data
No significant safety concerns were identified in preclinical studies.

6. Pharmaceutical Particulars
6.1 List of Excipients

- Lactos
- PVP
- Talc
- Mg Stearate

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
3 Years from the date of manufacture.

6.4 Special Precautions for Storage

- Store below 25°C in a dry place, protected from light.
- Keep out of reach of children.

6.5 Nature and Contents of Container
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 by the regulatory authority]

9. Date of First Authorization/Renewal of Authorization
[To be filled based on regulatory approval date]

10. Date of Revision of the Text
December 2024