1. NAME OF THE MEDICINAL PRODUCT
AC Motile Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains 2 mg of loperamide hydrochloride.

Excipients with known effect:
Lactose monohydrate: 150 mg per capsule.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsule.
Pale green and white, hard gelatin capsules containing a white or almost white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications
AC Motile Capsule is indicated for:

- Symptomatic treatment of acute diarrhea in adults and children aged 12 years and above.
- Management of chronic diarrhea in adults.

4.2 Posology and Method of Administration
Adults and children aged 12 years and above:

- Acute diarrhea: An initial dose of 2 capsules (4 mg), followed by 1 capsule (2 mg) after each loose stool. Maximum dose: 8 capsules (16 mg) per day.
- Chronic diarrhea: The initial dose is 2 capsules daily. Adjust dose to achieve 1–2 solid stools per day. Maximum dose: 8 capsules (16 mg) per day.

Children under 12 years:
Not recommended.

Method of administration:
For oral use. Capsules should be swallowed whole with water.

4.3 Contraindications

- Hypersensitivity to loperamide hydrochloride or any excipient listed in section 6.1.
- Acute dysentery characterized by blood in stools and high fever.
- Acute ulcerative colitis or pseudomembranous colitis associated with antibiotic use.
- Patients with bacterial enterocolitis caused by invasive organisms.

4.4 Special Warnings and Precautions for Use

- Should not be used as the primary therapy in severe diarrhea due to infection or colitis.
- Discontinue if abdominal distension, ileus, or constipation occurs.
- Use with caution in patients with hepatic impairment.
- Contains lactose; patients with galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction
Concomitant use with opioid analgesics may increase the risk of central nervous system (CNS) depression.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Not recommended during the first trimester.
- Lactation: Small amounts may be excreted in breast milk. Use only if the benefit outweighs the risk.

4.7 Effects on Ability to Drive and Use Machines
May cause dizziness or drowsiness. Patients should be cautioned about driving or operating machinery.

4.8 Undesirable Effects
Common: Constipation, nausea, flatulence, headache.
Rare: Ileus, hypersensitivity reactions, including rash and anaphylaxis.

4.9 Overdose
Symptoms: CNS depression, ileus, urinary retention.
Management: Administer naloxone and provide supportive care. Monitor for at least 48 hours for CNS depression recurrence.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic Properties
Pharmacotherapeutic group: Antidiarrheal, intestinal anti-inflammatory/anti-infective agents.
ATC code: A07DA03.

Loperamide binds to opioid receptors in the gut wall, reducing motility and increasing water and electrolyte absorption.

5.2 Pharmacokinetic Properties
Absorption: Poorly absorbed after oral administration.
Metabolism: Extensively metabolized in the liver.
Excretion: Mainly excreted in the feces.

5.3 Preclinical Safety Data
No significant findings in preclinical safety studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Starch
- Talc
- Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 Years

6.4 Special Precautions for Storage

Store in a cool, dry place below 25°C. Protect from light and moisture.

6.5 Nature and Contents of Container

Blister packs of 10 capsules/Blister

6.6 Special Precautions for Disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

To be assigned by the regulatory authority.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

To be completed upon approval.

10. DATE OF REVISION OF THE TEXT

December 2024