AC OME 20 (Omeprazole 20 mg Capsules)

1. **Name of the Medicinal Product**
AC OME 20 (Omeprazole 20 mg Capsules}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:
Active ingredient: Omeprazole 20 mg

Excipients:

- Omeprazole Dummy

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsule, hard.
Pink and white hard gelatin capsules imprinted with "AC OME 20."

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
AC OME 20 is indicated for:

- Treatment of gastric ulcers
- Treatment of duodenal ulcers
- Management of gastroesophageal reflux disease (GERD)
- Eradication of Helicobacter pylori in combination therapy

4.2 Posology and Method of Administration
Adults:

- GERD: 20 mg once daily for 4-8 weeks.
- Duodenal ulcers: 20 mg once daily for 2-4 weeks.
- Gastric ulcers: 20 mg once daily for 4-8 weeks.
- Helicobacter pylori eradication: 20 mg twice daily in combination with appropriate antibiotics for 1 week.

Paediatric population:
Not recommended for children under 12 years.

Method of administration:
Capsules should be swallowed whole with water, preferably before meals.

4.3 Contraindications

- Hypersensitivity to omeprazole or any excipients listed in section 6.1.
- Concomitant use with nelfinavir (a protease inhibitor).

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with severe hepatic impairment.
- Long-term use may increase the risk of gastric glandular cysts and hypomagnesaemia.
- Regular monitoring is advised for prolonged therapy.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- May reduce the absorption of drugs dependent on gastric pH (e.g., ketoconazole, itraconazole).
- Increases plasma levels of drugs metabolized by CYP2C19 (e.g., diazepam, warfarin).

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Use only if clearly needed and under medical supervision.
- Lactation: Omeprazole is excreted in breast milk; avoid use unless necessary.

4.7 Effects on Ability to Drive and Use Machines

Omeprazole has no or negligible influence on the ability to drive or use machines. However, dizziness and visual disturbances may occur.

4.8 Undesirable Effects

Common (≥1/100 to <1/10):

- Headache, nausea, abdominal pain, diarrhea, constipation.

Rare (≥1/10,000 to <1/1,000):

- Hepatic impairment, rash, pruritus.

Very rare (<1/10,000):

- Severe allergic reactions, Stevens-Johnson syndrome.

4.9 Overdose

Symptoms: Confusion, drowsiness, tachycardia.
Treatment: Symptomatic and supportive therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Proton pump inhibitors (ATC code: A02BC01)
Omeprazole inhibits gastric acid secretion by blocking the H+/K+-ATPase pump in gastric parietal cells.

5.2 Pharmacokinetic Properties

- Absorption: Rapid with peak plasma levels reached within 1-2 hours.
- Metabolism: Primarily hepatic via CYP2C19.
- Elimination: Half-life of approximately 1 hour; excreted in urine and feces.

5.3 Preclinical Safety Data

No significant findings in preclinical studies at therapeutic doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Omeprazole Dummy
- Gelatin Shell

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months.

6.4 Special Precautions for Storage

Store below 30°C in a dry place, protected from light.

6.5 Nature and Contents of Container

AC OME 20 is supplied in blister packs containing 14 capsules.

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

03 December 2024