1. NAME OF THE MEDICINAL PRODUCT
Acithromac Tablet 500 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:
Active Ingredient: Erythromycin Stearate 500 mg.

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

3. PHARMACEUTICAL FORM
Film-coated tablet.
White, oval-shaped tablets with a break-line on one side for easy division.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
Acithromac Tablet is indicated for the treatment of infections caused by susceptible strains of microorganisms, including:

- Upper and lower respiratory tract infections (e.g., pharyngitis, bronchitis, pneumonia).
- Skin and soft tissue infections (e.g., impetigo, cellulitis).
- Gastrointestinal infections caused by Campylobacter jejuni.
- Whooping cough caused by Bordetella pertussis.
- Prophylaxis of rheumatic fever in penicillin-allergic patients.

4.2 Posology and Method of Administration
Adults: 250 mg every 6 hours or 500 mg every 12 hours. For severe infections, the dose may be increased to 4 g daily.
Paediatric population: Not recommended for children under 12 years.
Elderly: No dose adjustment is required unless significant renal or hepatic impairment is present.

Administer orally with or without food. Swallow tablets whole with a glass of water.

4.3 Contraindications
- Hypersensitivity to erythromycin or any macrolide antibiotic.
- Severe hepatic impairment.
- Concurrent use with drugs highly dependent on CYP3A4 for metabolism (e.g., cisapride, pimozide).

4.4 Special Warnings and Precautions for Use
- Use with caution in patients with impaired hepatic or renal function.
- May prolong QT interval. Avoid in patients with a history of QT prolongation or uncorrected electrolyte disturbances.
- Monitor for signs of superinfection with non-susceptible organisms during prolonged therapy.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Concomitant use with statins (e.g., simvastatin, atorvastatin) may increase the risk of myopathy or rhabdomyolysis.
- Avoid use with potent CYP3A inhibitors (e.g., ketoconazole, clarithromycin).
- May reduce the efficacy of oral contraceptives.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Erythromycin crosses the placenta but has not shown teratogenic effects. Use only if clearly needed.
- Lactation: Erythromycin is excreted in breast milk. Caution is advised.

4.7 Effects on Ability to Drive and Use Machines
Acithromac Tablet has no known effects on the ability to drive or use machines.

4.8 Undesirable Effects
Common adverse reactions include:

- Gastrointestinal: nausea, vomiting, abdominal pain, diarrhea.
- Hepatobiliary: transient liver enzyme elevations, cholestatic hepatitis.
- Others: rash, pruritus, hearing loss (rare).

4.9 Overdose
Symptoms: Severe gastrointestinal distress, reversible ototoxicity.
Treatment: Gastric lavage, supportive measures, and symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic Properties
Pharmacotherapeutic group: Macrolides, ATC Code: J01FA01.
Mechanism of action: Inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit.

5.2 Pharmacokinetic Properties
- Absorption: Well-absorbed orally but affected by gastric pH. Peak plasma concentrations occur 1-2 hours post-dose.
- Distribution: Widely distributed in tissues and fluids; minimal penetration into cerebrospinal fluid.
- Metabolism: Hepatic.
- Elimination: Excreted primarily in bile and feces; 5-15% excreted unchanged in urine.

5.3 Preclinical Safety Data
No evidence of mutagenicity, carcinogenicity, or teratogenicity in animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Starch
- Mg Stearate
- Talc
- Na benzoate
- Cross Carmellose
- SSG
- Gelatin

6.2 Incompatibilities

None reported.

6.3 Shelf Life

3 years

6.4 Special Precautions for Storage

Store in a cool, dry place below 30°C. Protect from light and moisture.

6.5 Nature and Contents of Container

Blister packs of 10 tablets.
Caplet tablet with line at one side

6.6 Special Precautions for Disposal

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

[To be assigned by the regulatory authority]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

[To be assigned]

10. DATE OF REVISION OF THE TEXT

December 2024