1. NAME OF THE MEDICINAL PRODUCT
AC Fed Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

- Chlorphenamine Maleate: 4 mg

3. PHARMACEUTICAL FORM
Tablet.
Description: Yellow, round, flat tablets with a scored line on one side.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
AC Fed Tablets are indicated for the symptomatic relief of:

- Allergic conditions, including rhinitis, conjunctivitis, and urticaria.
- Hay fever and perennial allergic rhinitis.
- Pruritic skin conditions such as eczema, dermatitis, and insect bites.

4.2 Posology and Method of Administration
Adults and children over 12 years:
4 mg (1 tablet) every 4 to 6 hours. Maximum daily dose: 24 mg (6 tablets).

Children (6–12 years):
2 mg (half a tablet) every 4 to 6 hours. Maximum daily dose: 12 mg.

Children under 6 years:
Not recommended.

Elderly:
Use with caution. Start with the lowest effective dose.

Route of Administration: Oral, with or without food.

4.3 Contraindications

- Hypersensitivity to Chlorphenamine Maleate or any of the excipients.
- Use in patients with narrow-angle glaucoma, severe hypertension, or urinary retention.
- Use in neonates or premature infants.

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with asthma, epilepsy, prostatic hypertrophy, or hepatic impairment.
- Avoid use with alcohol or other central nervous system depressants.
- May cause drowsiness; advise against driving or operating machinery.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Alcohol and CNS depressants: Potentiation of sedation.
- Monoamine oxidase inhibitors (MAOIs): Prolonged anticholinergic effects; avoid concomitant use.
- Phenytoin: Reduced clearance of phenytoin may occur.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Use only if potential benefits outweigh risks; limited data on use in pregnancy.
- Lactation: Small amounts of Chlorphenamine may pass into breast milk; not recommended during breastfeeding.

4.7 Effects on Ability to Drive and Use Machines

Chlorphenamine may cause drowsiness, dizziness, or blurred vision. Patients should be cautioned against driving or using machinery until they know how the drug affects them.

4.8 Undesirable Effects

Common side effects:

- Drowsiness, dizziness, headache, dry mouth, and nausea.
- Less common: Blurred vision, difficulty urinating, and gastrointestinal disturbances.

Report adverse effects to AC Drugs Limited via the provided contact details.

4.9 Overdose

Symptoms: Drowsiness, ataxia, dry mouth, respiratory depression, and convulsions.
Management: Supportive care and symptomatic treatment. Activated charcoal may reduce absorption if given early.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Mechanism of Action:
Chlorphenamine is a first-generation antihistamine that blocks H1 histamine receptors, reducing allergic symptoms such as itching, swelling, and congestion.

5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed from the gastrointestinal tract; onset of action within 30 minutes.
- Distribution: Widely distributed in body tissues, crosses the blood-brain barrier.
- Metabolism: Metabolized in the liver.
- Excretion: Excreted primarily in urine; half-life is approximately 12-15 hours.

5.3 Preclinical Safety Data
No relevant preclinical data available beyond those already addressed in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS
6.1 List of Excipients

- Lactose monohydrate
- Starch
- Gelatin
- Methyl
- Propyl
- Talc
- Mg Stearate

6.2 Incompatibilities
None known.

6.3 Shelf Life
3 Years

6.4 Special Precautions for Storage
Store below 30°C in a cool, dry place, away from direct sunlight. Keep out of reach of children.

6.5 Nature and Contents of Container
AC Fed Tablets are available in blister packs of 10 tablets.

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
[To be provided upon regulatory approval]

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION
[To be specified]

10. DATE OF REVISION OF THE TEXT
December 2024