1. NAME OF THE MEDICINAL PRODUCT
AC Mol Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml contains:

- Paracetamol: 100mg/1ml

Excipients with known effect: [Specify excipients if applicable, e.g., preservatives like methylparaben].

3. PHARMACEUTICAL FORM
Oral drops.
Description: Clear, colorless to pale yellow liquid, contained in a 15 ml amber glass bottle with a dropper.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
AC Mol Drops are indicated for the relief of mild to moderate pain and fever in:

- Teething
- Post-immunization fever
- Headache
- Earache
- Sore throat

4.2 Posology and Method of Administration
Posology:

- Infants (3 months to 1 year): 0.6 ml to 1.2 ml (60-120 mg) every 4-6 hours, as needed.
- Children (1-6 years): 1.2 ml to 2.4 ml (120-240 mg) every 4-6 hours, as needed.

Maximum daily dose: Do not exceed 4 doses in 24 hours.

Route of Administration:
Oral. Administer using the dropper provided with the product.

4.3 Contraindications
- Hypersensitivity to Paracetamol or any excipients.
- Severe hepatic impairment.

4.4 Special Warnings and Precautions for Use

- Prolonged or excessive use may lead to liver damage.
- Use with caution in patients with impaired liver or kidney function.
- Avoid concurrent use with other products containing Paracetamol.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Warfarin and other anticoagulants: Prolonged use may enhance the risk of bleeding.
- Enzyme-inducing drugs: May increase the risk of hepatotoxicity (e.g., rifampin, carbamazepine).

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Paracetamol is generally safe when used as recommended.
- Lactation: Trace amounts are excreted in breast milk but are not clinically significant.

4.7 Effects on Ability to Drive and Use Machines

Paracetamol has no known effects on the ability to drive or use machinery.

4.8 Undesirable Effects

Adverse effects are rare when used at recommended doses.

- Common: None.
- Rare: Allergic reactions (rash, pruritus, anaphylaxis), liver dysfunction.

Report any adverse reactions to AC Drugs Limited via the provided contact information.

4.9 Overdose

Symptoms: Nausea, vomiting, sweating, and abdominal pain within 24 hours of ingestion. Severe overdose may lead to liver failure.
Management: Immediate medical attention is required. Administer activated charcoal within 1 hour of ingestion and consider acetylcysteine as an antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Mechanism of Action: Paracetamol is an analgesic and antipyretic that inhibits prostaglandin synthesis in the central nervous system.

5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed from the gastrointestinal tract.
- Distribution: Distributed into most body tissues; crosses the placenta and is present in breast milk.
- Metabolism: Metabolized in the liver to glucuronide and sulfate conjugates.
- Excretion: Primarily excreted in urine as metabolites.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Methyl
- Sugar
- IPA
- Propyl
- Citric Acid
- Na citrate
- Na EDTA
- CMC
- Carmosine red
- Flavour
- Propylene Glycol

6.2 Incompatibilities

None known.

6.3 Shelf Life

2 Years.

6.4 Special Precautions for Storage

Store below 30°C in a dry place, protected from light. Keep out of reach of children.

6.5 Nature and Contents of Container

1 bottle per packet .

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