1. NAME OF THE MEDICINAL PRODUCT
AC Drex Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

- Paracetamol 500 mg
- Caffeine (Anhydrous - 30 mg

Excipient(s): For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablet.
White and pink, round, biconvex tablets packaged in a blister pack containing 10 tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
AC Drex Tablets are indicated for the relief of mild to moderate pain including headache, migraine, toothache, menstrual pain, and musculoskeletal discomfort. It is also effective for reducing fever.

4.2 Posology and Method of Administration
Adults and adolescents (12 years and older):

- One to two tablets every 4 to 6 hours as required.
- Maximum daily dose: 8 tablets (4000 mg paracetamol, 240 mg caffeine).

Children under 12 years:

- Not recommended.

Method of Administration:
For oral use. Swallow with water.

4.3 Contraindications

- Hypersensitivity to paracetamol, caffeine, or any excipient.
- Severe hepatic impairment or active liver disease.

4.4 Special Warnings and Precautions for Use

- Do not exceed the stated dose.
- Prolonged use of high doses may lead to liver damage.
- Caution in patients with renal or hepatic impairment.
- Excessive caffeine intake may cause nervousness, irritability, and rapid heart rate.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Paracetamol may interact with anticoagulants (e.g., warfarin) when taken long-term.
- Caffeine may enhance the effect of central nervous system stimulants.
- Avoid concomitant use with other paracetamol-containing products.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Use with caution. Consult a healthcare provider.
- Lactation: Caffeine may be excreted in breast milk. Use only if necessary.

4.7 Effects on Ability to Drive and Use Machines

Unlikely to impair driving or machine use.

4.8 Undesirable Effects

- Common: Nausea, headache, insomnia (due to caffeine).
- Rare: Allergic reactions, skin rashes, and liver damage with overdose.

4.9 Overdose

Paracetamol: May cause hepatotoxicity. Treat with N-acetylcysteine or methionine.
Caffeine: Symptoms include restlessness, insomnia, and tachycardia. Provide supportive care.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

- Paracetamol: Analgesic and antipyretic. Acts centrally to block pain signals and reduce fever.
- Caffeine: Enhances the analgesic effect of paracetamol and stimulates the central nervous system.

5.2 Pharmacokinetic Properties

- Paracetamol: Rapidly absorbed; metabolized in the liver and excreted in urine.
- Caffeine: Absorbed quickly; metabolized in the liver; excreted in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Starch
- Methyl
- Propyl
- Gelatin
- SSG
- PVP
- Mg Stearate
- Talc
- Sunset Yellow

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
3 years from the date of manufacture.

6.4 Special Precautions for Storage
Store below 25°C. Protect from moisture and direct sunlight.

6.5 Nature and Contents of Container
Blister pack of 10 tablets.

6.6 Special Precautions for Disposal
No special requirements. Dispose of 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(S)
To be assigned by the regulatory authority.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION
To be assigned by the regulatory authority.

10. DATE OF REVISION OF THE TEXT
December 2024.