BRAND NAME: ACD 500

Active Ingredient: Paracetamol 500 mg
Marketing Authorization Holder: AC Drugs Limited

1. NAME OF THE MEDICINAL PRODUCT
ACD 500 (Paracetamol 500 mg tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains 500 mg of Paracetamol.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablet.
White, round, flat tablets with a break line ACD 500 debosed on that side.

4. CLINICAL PARTICULARS
4.1 Therapeutic Indications
ACD 500 is indicated for the relief of mild to moderate pain and fever, including:

- Headache
- Toothache
- Muscular pain
- Fever associated with colds and flu

4.2 Posology and Method of Administration

- Adults and Adolescents (over 12 years):
- 500–1000 mg (1–2 tablets) every 4–6 hours as needed.
- Maximum dose: 4000 mg (8 tablets) in 24 hours.
- Children (6–12 years):
- 250–500 mg (½ to 1 tablet) every 4–6 hours as needed.
- Maximum dose: 2000 mg (4 tablets) in 24 hours.
- Children under 6 years:
- Not recommended.

Method of Administration:
Oral use. Tablets should be swallowed whole with water.

4.3 Contraindications

- Hypersensitivity to paracetamol or any excipient listed in section 6.1.
- Severe liver disease.

4.4 Special Warnings and Precautions for Use

- Do not exceed the recommended dose.
- Use with caution in patients with hepatic or renal impairment.
- Avoid concomitant use with other paracetamol-containing medications.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Increased risk of hepatotoxicity with alcohol or hepatotoxic drugs.
- Enhanced effect of anticoagulants such as warfarin with prolonged regular use.

4.6 Fertility, Pregnancy, and Lactation

- Paracetamol can be used during pregnancy if clinically needed.
- Small amounts are excreted in breast milk but are not considered harmful to the infant.

4.7 Effects on Ability to Drive and Use Machines

None.

4.8 Undesirable Effects

Common: None.
Rare: Allergic reactions (rash, angioedema).
Very rare: Hepatic dysfunction.

4.9 Overdose

Symptoms: Nausea, vomiting, abdominal pain, and hepatotoxicity.
Management: Immediate medical attention is required. Administer activated charcoal or N-acetylcysteine (NAC).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

ATC Code: N02BE01
Paracetamol exhibits analgesic and antipyretic effects via inhibition of prostaglandin synthesis in the CNS.

5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed from the gastrointestinal tract.
- Metabolism: Metabolized in the liver.
- Excretion: Excreted via the urine, primarily as conjugates.

5.3 Preclinical Safety Data
No significant preclinical safety concerns at therapeutic doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Starch
- Gelatin
- Propyl Paraben
- Methyl Paraben
- Lactose

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
3 years.

6.4 Special Precautions for Storage
Store below 25°C. Keep in the original packaging to protect from light.

6.5 Nature and Contents of Container
Blister packs of 10, 20, or 100 tablets.

6.6 Special Precautions for Disposal
No special requirements. Dispose of unused product in accordance with local regulations.

7. MARKETING AUTHORISATION HOLDER

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