1. Name of the Medicinal Product
Ac Diclo 100 mg Tablet

2. Qualitative and Quantitative Composition
Each tablet contains:
Active Ingredient: Diclofenac Sodium 100 mg.

Excipient(s) with known effects: [Specify if applicable, e.g., lactose monohydrate].

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Tablet.

Description: [Specify physical characteristics of the tablet, e.g., "white, oval-shaped tablet with a scored line on one side."]

4. Clinical Particulars
4.1 Therapeutic Indications

- Relief of pain and inflammation in conditions such as osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and acute musculoskeletal disorders.
- Management of acute gout, dysmenorrhea, and postoperative pain.

4.2 Posology and Method of Administration

- Adults: One tablet (100 mg) once daily, preferably with food.
- Elderly: Dosage adjustment may be necessary. Use with caution.
- Pediatric population: Not recommended for children under 12 years of age.

Method of administration:
Oral use. Swallow whole with a glass of water.

4.3 Contraindications

- Hypersensitivity to diclofenac or any of the excipients.
- Active gastric or intestinal ulcer, bleeding, or perforation.
- Severe hepatic, renal, or cardiac failure.
- Third trimester of pregnancy.

4.4 Special Warnings and Precautions for Use

- Use with caution in patients with a history of gastrointestinal bleeding or ulceration.
- Monitor liver and kidney function in long-term treatment.
- Avoid use in patients with severe heart failure.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Increased risk of bleeding with anticoagulants and antiplatelet agents.
- Reduced efficacy of antihypertensives such as ACE inhibitors or beta-blockers.
- Increased plasma concentration of lithium or digoxin.

4.6 Fertility, Pregnancy, and Lactation

- Contraindicated in the third trimester of pregnancy.
- Use during breastfeeding is not recommended.

4.7 Effects on Ability to Drive and Use Machines

May cause dizziness or drowsiness. Caution patients about driving or operating machinery.

4.8 Undesirable Effects

- Common: Nausea, dyspepsia, abdominal pain, diarrhea.
- Rare: Hepatotoxicity, renal impairment, or anaphylactic reactions.

4.9 Overdose

- Symptoms: Nausea, vomiting, gastrointestinal bleeding, renal failure.
- Management: Symptomatic and supportive care. Activated charcoal may be considered.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

ATC code: M01AB05.
Mechanism of action: Diclofenac sodium inhibits cyclooxygenase (COX-1 and COX-2), reducing prostaglandin synthesis and inflammation.

5.2 Pharmacokinetic Properties

Absorption: Rapidly absorbed after oral administration.
Distribution: Protein binding >99%.
Metabolism: Primarily metabolized in the liver via CYP2C9.
Elimination: Excreted in urine and bile. Half-life: 1-2 hours.

5.3 Preclinical Safety Data

Animal studies show gastrointestinal toxicity at high doses. No evidence of mutagenicity or carcinogenicity.

6. Pharmaceutical Particulars

6.1 List of Excipients

- Starch
- Na benzoate
- Gelatin
- Talc
- Mg Stearate
- Sunset Yellow

6.2 Incompatibilities
Not applicable.

6.3 Shelf Life
3 years.

6.4 Special Precautions for Storage
Store below 30°C. Protect from light and moisture.

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

6.6 Special Precautions for Disposal
No special requirements.

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

8. Marketing Authorization Number(s)
[To be filled by the regulatory authority upon approval.]

9. Date of First Authorization/Renewal of the Authorization
[Insert date.]

10. Date of Revision of the Text
December 2024