## 1. NAME OF THE MEDICINAL PRODUCT
AC Diclo 50

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains:

- Diclofenac Sodium: 50 mg

## 3. PHARMACEUTICAL FORM
Tablet.
Description: Orange, round, film-coated tablets with a smooth surface.

## 4. CLINICAL PARTICULARS
### 4.1 Therapeutic Indications
AC Diclo 50 is indicated for the treatment of:

- Pain and inflammation in musculoskeletal disorders (e.g., rheumatoid arthritis, osteoarthritis, ankylosing spondylitis)
- Acute gout
- Post-traumatic and post-operative pain, inflammation, and swelling
- Dysmenorrhea (painful menstrual periods)
- Mild to moderate pain, including dental and back pain

### 4.2 Posology and Method of Administration
Adults and adolescents over 14 years:

- The recommended dose is 50 mg taken two to three times daily.
- Maximum daily dose: 150 mg.

**Elderly (over 65 years):**

- Use the lowest effective dose due to increased risk of adverse effects.

**Children under 14 years:**

- Not recommended for this age group.

**Route of Administration:**

- Oral. Tablets should be swallowed whole with water, preferably before meals.

### 4.3 Contraindications

- Hypersensitivity to Diclofenac or any excipient in the formulation.
- Active gastric or duodenal ulcer, bleeding, or perforation.

- History of asthma, urticaria, or other allergic reactions after taking NSAIDs.
- Severe renal, hepatic, or cardiac failure.
- Last trimester of pregnancy.

**4.4 Special Warnings and Precautions for Use**

- Cardiovascular Risk: Increased risk of thrombotic events, myocardial infarction, and stroke, especially with prolonged use or high doses.
- Gastrointestinal Risk: Monitor for signs of gastrointestinal bleeding, ulceration, or perforation, particularly in elderly patients.
- Hepatic and Renal Effects: Monitor liver function tests and renal parameters in patients with hepatic or renal impairment.
- Use with caution in patients with hypertension, heart failure, or a history of gastrointestinal disease.

**4.5 Interaction with Other Medicinal Products and Other Forms of Interaction**

- Anticoagulants (e.g., warfarin): Increased risk of bleeding.
- Corticosteroids: Increased risk of gastrointestinal ulcers or bleeding.
- Diuretics and ACE inhibitors: May reduce efficacy and increase risk of renal dysfunction.
- Lithium and Methotrexate: Increased plasma concentrations and toxicity.
- Avoid concomitant use with other NSAIDs.

**4.6 Fertility, Pregnancy, and Lactation**

- Pregnancy: Contraindicated in the third trimester due to risk of premature closure of the ductus arteriosus.
- Lactation: Small amounts of Diclofenac are excreted in breast milk; use with caution.
- Fertility: May impair female fertility; avoid in women trying to conceive.

**4.7 Effects on Ability to Drive and Use Machines**

Dizziness, drowsiness, or visual disturbances may occur. Patients should avoid driving or operating machinery if affected.

**4.8 Undesirable Effects**

Common adverse effects include:

- Gastrointestinal: Nausea, vomiting, abdominal pain, diarrhea, dyspepsia.
- Central nervous system: Headache, dizziness.
- Skin: Rash, pruritus.
- Rare: Peptic ulcer, gastrointestinal bleeding, anaphylaxis, liver enzyme elevation.

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

### 4.9 Overdose

Symptoms: Nausea, vomiting, gastrointestinal bleeding, renal failure, drowsiness, or convulsions.
Management: Supportive care, gastric lavage, activated charcoal, and symptomatic treatment as needed.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

Mechanism of Action: Diclofenac Sodium is a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory, and antipyretic properties. It inhibits cyclooxygenase (COX-1 and COX-2), reducing prostaglandin synthesis.

### 5.2 Pharmacokinetic Properties

- Absorption: Rapidly absorbed; peak plasma levels occur within 2 hours after oral administration.
- Distribution: Highly protein-bound (~99%).
- Metabolism: Metabolized in the liver via hydroxylation and conjugation.
- Excretion: Excreted mainly in the urine (~60%) and bile (~40%).

### 5.3 Preclinical Safety Data

No evidence of carcinogenicity or mutagenicity in animal studies.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

- Lactose
- Starch
- Na Benzoate
- Gelatin
- Mg Stearate

**For Coating**

- HPMC
- IPA
- Methylene Chloride
- Talc
- Titanum Dioxide
- Sunset Yellow Lake

### 6.2 Incompatibilities

None known.

### 6.3 Shelf Life

3 Years

**6.4 Special Precautions for Storage**
Store below 30°C in a dry place, away from direct sunlight. 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