# Product Name: AC Tramadol 100 mg Capsules

Manufacturer: AC Drugs Limited
Address: Plot C5/C6, Old Airport Road, Emene, Enugu State, Nigeria

## 1. NAME OF THE MEDICINAL PRODUCT
AC Tramadol 100 mg Capsules

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Active Substance: Each capsule contains 100 mg of Tramadol Hydrochloride.

Excipients: Refer to Section 6.1 for a full list of excipients.

## 3. PHARMACEUTICAL FORM
Capsule, hard.
Opaque yellow and green capsule filled with off-white powder.

## 4. CLINICAL PARTICULARS
### 4.1 Therapeutic Indications
AC Tramadol is indicated for the management of moderate to severe pain in adults and children over 12 years of age.

### 4.2 Posology and Method of Administration
- Adults and adolescents over 12 years:

One capsule (100 mg) every 4-6 hours as needed. The maximum daily dose should not exceed 400 mg.
- Elderly: Dose adjustment may be required based on renal or hepatic function.
- Paediatric population: Not recommended for children under 12 years.
- Method of administration: Oral. The capsules should be swallowed whole with water.

### 4.3 Contraindications
- Hypersensitivity to Tramadol or any excipient in the formulation.
- Acute intoxication with alcohol, hypnotics, analgesics, opioids, or psychotropic drugs.
- Severe respiratory depression or uncontrolled epilepsy.

### 4.4 Special Warnings and Precautions for Use

- Use with caution in patients with a history of substance abuse or dependence.
- Risk of serotonin syndrome when co-administered with serotonergic drugs.
- Caution in patients with impaired renal or hepatic function.

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

- Enhanced central nervous system (CNS) depression with alcohol or CNS depressants.
- Increased risk of seizures with selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), or tricyclic antidepressants.
- Avoid use with monoamine oxidase inhibitors (MAOIs).

**4.6 Fertility, Pregnancy, and Lactation**

- Pregnancy: Use only if the potential benefit justifies the potential risk.
- Lactation: Not recommended as Tramadol is excreted in breast milk.

**4.7 Effects on Ability to Drive and Use Machines**
May impair mental and physical abilities. Patients should avoid driving or operating machinery.

**4.8 Undesirable Effects**
- Common: Nausea, dizziness, constipation, headache, somnolence.
- Rare: Seizures, respiratory depression, anaphylactic reactions.

**4.9 Overdose**
Symptoms include respiratory depression, somnolence, convulsions, and cardiac arrest. Treatment includes supportive care, with naloxone as an antidote for respiratory depression.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic Properties**

- Pharmacotherapeutic group: Opioid analgesic.
- Mechanism of action: Tramadol acts on opioid receptors and inhibits the reuptake of norepinephrine and serotonin.

**5.2 Pharmacokinetic Properties**

- Absorption: Rapidly absorbed with oral bioavailability of 70-90%.
- Distribution: Volume of distribution is approximately 2.7 L/kg.
- Metabolism: Metabolized in the liver via CYP2D6 and CYP3A4.
- Elimination: Eliminated via the kidneys; elimination half-life is approximately 6 hours.

**5.3 Preclinical Safety Data**
No evidence of mutagenic, carcinogenic, or teratogenic effects in animal studies at therapeutic doses.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

- Starch
- Magnesium stearate
- Talc
- Gelatin (capsule shell)
- Aerosil
- Na Laurel $50_4$

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

36 months when stored under recommended conditions.

### 6.4 Special Precautions for Storage

Store below 30°C in a dry place. Keep out of reach of children.

### 6.5 Nature and Contents of Container

Available in blister packs of 10 capsules.

### 6.6 Special Precautions for Disposal

No special disposal requirements.

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

(To be assigned by the regulatory authority.)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

(To be completed upon regulatory approval.)

## 10. DATE OF REVISION OF THE TEXT

December 2024