1. Name of the Medicinal Product
AC Ciprotinad (Ciprofloxacin 500 mg + Tinidazole 600 mg Tablets)

2. Qualitative and Quantitative Composition
Each film-coated tablet contains:

- Ciprofloxacin hydrochloride equivalent to 500 mg of Ciprofloxacin
- Tinidazole 600 mg

Excipients: See section 6.1 for a full list.

3. Pharmaceutical Form
Film-coated tablet.

- Description: Yellow, oblong, biconvex tablets engraved with “ACD” on one side.

4. Clinical Particulars
4.1 Therapeutic Indications
AC Ciprotinad is indicated for the treatment of infections caused by susceptible organisms, including:

- Mixed infections caused by anaerobic and aerobic bacteria (e.g., gynecological infections, intra-abdominal infections).
- Gastrointestinal infections (e.g., amoebiasis, giardiasis, infectious diarrhea).
- Urinary tract infections (complicated and uncomplicated).

4.2 Posology and Method of Administration
Adults and Adolescents (≥18 years):

- Recommended dose: One tablet (Ciprofloxacin 500 mg + Tinidazole 600 mg) twice daily for 5–14 days depending on the severity and type of infection.

Route of Administration: Oral.

- Tablets should be swallowed whole with a glass of water.
- Should be taken after meals to minimize gastrointestinal upset.

Special Populations:

- Renal impairment: Adjust Ciprofloxacin dosage if creatinine clearance <30 mL/min.
- Hepatic impairment: No dose adjustment required for Tinidazole.

4.3 Contraindications

- Hypersensitivity to Ciprofloxacin, Tinidazole, or any quinolone or nitroimidazole derivatives.
- History of tendon disorders related to quinolone use.
- Pregnancy and breastfeeding.
- Severe central nervous system disorders (e.g., epilepsy).

4.4 Special Warnings and Precautions for Use

- Tendon Rupture: Avoid in patients with a history of tendon disorders. Discontinue if pain or swelling occurs.
- Neurological Effects: Use with caution in patients with CNS disorders.
- Photosensitivity: Advise patients to avoid direct sunlight or UV exposure.
- Clostridioides difficile-associated diarrhea: Discontinue use if severe diarrhea occurs.
- Peripheral Neuropathy: Monitor for symptoms, especially during prolonged use.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- Antacids and Sucralfate: Reduce Ciprofloxacin absorption; administer 2 hours apart.
- Warfarin: Increased anticoagulant effect; monitor INR.
- Alcohol: Avoid concurrent use with Tinidazole due to disulfiram-like reactions.

4.6 Fertility, Pregnancy, and Lactation

- Pregnancy: Contraindicated due to potential teratogenic effects.
- Breastfeeding: Discontinue breastfeeding due to excretion of both drugs in breast milk.

4.7 Effects on Ability to Drive and Use Machines

May cause dizziness, drowsiness, or visual disturbances. Patients should not drive or operate machinery if affected.

4.8 Undesirable Effects

Common: Nausea, diarrhea, abdominal pain, headache, dizziness.
Uncommon: Photosensitivity, myalgia, fatigue, metallic taste.
Rare: Tendon rupture, peripheral neuropathy, severe allergic reactions.

Report adverse reactions to the pharmacovigilance team at AC Drugs Limited.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

- Ciprofloxacin: A fluoroquinolone with bactericidal activity by inhibiting bacterial DNA gyrase.
- Tinidazole: A nitroimidazole with antiprotozoal and antibacterial effects via DNA disruption.

5.2 Pharmacokinetic Properties

- Ciprofloxacin: Bioavailability ~70%; peak plasma concentration 1–2 hours.
- Tinidazole: Bioavailability ~100%; peak plasma concentration 2 hours.

6. Pharmaceutical Particulars
6.1 List of Excipients

- Starch
- Gelatin
- Methyl
- Propyl
- Mg Stearate
- Talc

6.2 Shelf Life
3 Years from the date of manufacture.

6.3 Special Precautions for Storage
Store in a cool, dry place at temperatures below 30°C. Protect from light and moisture.

6.4 Nature and Contents of Container
Blister packs of 10 tablets.

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

8. Marketing Authorization Number
To be assigned by the regulatory agency.

9. Date of Revision of the Text
11 December 2024