SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Cafloxin 500 mg Caplet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each caplet contains Ciprofloxacin hydrochloride equivalent to Ciprofloxacin 500 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated caplet.

White, oblong, film-coated caplet embossed with “CDL” on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ciprofloxacin should be reserved for infections for which other commonly recommended antibacterial agents are inappropriate, taking account of the risk of prolonged, disabling and potentially irreversible serious adverse reactions and current susceptibility information.

In adults, ciprofloxacin 500 mg tablets are indicated, where clinically appropriate, for susceptible bacterial infections including:

• lower respiratory tract infections due to Gram-negative bacteria;

• chronic suppurative otitis media;

• acute exacerbation of chronic sinusitis due particularly to Gram-negative bacteria;

• uncomplicated acute cystitis where other recommended agents are inappropriate;

• acute and complicated pyelonephritis;

• complicated urinary tract infections;

• bacterial prostatitis;

• susceptible genital tract infections;

• gastrointestinal and intra-abdominal infections;

• skin and soft-tissue infections caused by Gram-negative bacteria;

• malignant external otitis;

• bone and joint infections;

• prophylaxis of invasive Neisseria meningitidis infection;

• inhalational anthrax post-exposure prophylaxis and curative treatment.

Ciprofloxacin may also be used in neutropenic patients with fever suspected to be due to bacterial infection, with appropriate antibacterial co-therapy where indicated.

In children and adolescents, use is restricted to selected indications such as Pseudomonas aeruginosa broncho-pulmonary infection in cystic fibrosis, complicated urinary tract infection/acute pyelonephritis and inhalational anthrax, or other severe infections where specialist assessment determines that treatment is necessary. Official antibacterial guidance should be considered.

4.2 Posology and method of administration

Posology

Dose and treatment duration depend on the indication, severity and site of infection, susceptibility of the causative organism, renal function and, in children/adolescents, body weight.

Adults

Commonly 500 mg twice daily; some severe infections require 750 mg twice daily. Typical treatment durations range from 1 day for selected gastrointestinal indications to several weeks or longer for certain prostatitis, bone/joint and malignant external otitis indications. The exact regimen should follow the indication-specific dosing schedule and current official guidance.

Renal impairment

Dose reduction is required according to creatinine clearance. For creatinine clearance 30–60 mL/min/1.73 m², 250–500 mg every 12 hours is recommended; for ≤30 mL/min/1.73 m², 250–500 mg every 24 hours. Patients receiving haemodialysis or peritoneal dialysis generally receive 250–500 mg every 24 hours, with administration after haemodialysis where applicable.

Hepatic impairment

No dose adjustment is generally required.

Elderly

Select the dose according to infection severity and creatinine clearance.

Paediatric population

Paediatric dosing is weight-based and specialist-supervised for approved indications.

Method of administration

Swallow the caplets unchewed with fluid. They may be taken independently of meals. Avoid taking with dairy products or mineral-fortified drinks taken alone. Where oral administration is not possible or infection is severe, intravenous ciprofloxacin may be used initially before switching to oral treatment.

4.3 Contraindications

Hypersensitivity to ciprofloxacin, other quinolones or any of the excipients listed in section 6.1.

Concomitant administration with tizanidine.

4.4 Special warnings and precautions for use

Fluoroquinolones, including ciprofloxacin, can cause prolonged, disabling and potentially irreversible adverse reactions involving musculoskeletal, nervous, psychiatric and sensory systems. Ciprofloxacin should be discontinued at the first signs of a serious adverse reaction and alternative treatment considered.

Use should generally be avoided in patients who have previously experienced serious quinolone/fluoroquinolone adverse reactions unless no suitable alternative exists and a careful benefit-risk assessment supports treatment.

Fluoroquinolones have been associated with aortic aneurysm/dissection and heart-valve regurgitation/incompetence. Consider alternative therapy in patients with relevant risk factors and advise urgent medical assessment for sudden chest, abdominal or back pain or acute dyspnoea/palpitations/oedema.

Ciprofloxacin monotherapy is unsuitable for severe infections or infections likely to involve Gram-positive or anaerobic organisms; appropriate combination therapy may be required.

Local resistance patterns should be considered, particularly for urinary, genital and severe infections.

Tendinitis and tendon rupture, especially involving the Achilles tendon, can occur during or after treatment. Risk is increased in older patients, renal impairment, organ transplantation and concomitant corticosteroid use. Avoid corticosteroids where tendinopathy occurs.

Use cautiously in myasthenia gravis, seizure disorders/CNS disease, QT-prolongation risk, diabetes, renal impairment, hepatic disease and glucose-6-phosphate dehydrogenase deficiency.

Severe or persistent diarrhoea may indicate antibiotic-associated colitis; ciprofloxacin should be stopped and appropriate treatment instituted.

Patients should maintain adequate hydration and avoid excessive urine alkalinity because crystalluria can occur.

Ciprofloxacin inhibits CYP1A2 and may increase exposure to substrates including theophylline, tizanidine, clozapine, olanzapine, ropinirole, duloxetine and agomelatine.

Resistance may develop during or after therapy, particularly with prolonged treatment or infections involving hospital-acquired pathogens, Staphylococcus or Pseudomonas species.

4.5 Interaction with other medicinal products and other forms of interaction

Multivalent cation-containing medicines/mineral supplements (calcium, magnesium, aluminium or iron), antacids, sucralfate, polymeric phosphate binders and certain buffered preparations reduce ciprofloxacin absorption. Administer ciprofloxacin 1–2 hours before or at least 4 hours after these preparations.

Dairy products and mineral-fortified drinks taken alone may reduce absorption and should not be taken concurrently.

Probenecid increases ciprofloxacin concentrations by reducing renal secretion.

Metoclopramide accelerates absorption without reducing overall bioavailability.

Omeprazole causes a small reduction in ciprofloxacin exposure.

Tizanidine is contraindicated with ciprofloxacin because of a marked increase in tizanidine exposure and associated hypotension and sedation.

Methotrexate co-administration is not recommended because ciprofloxacin may reduce renal tubular transport of methotrexate and increase toxicity.

Ciprofloxacin may increase theophylline concentrations; monitor levels and adjust theophylline dose as necessary.

Phenytoin concentrations may increase or decrease; monitoring is recommended.

Ciprofloxacin may transiently increase serum creatinine with ciclosporin.

Vitamin K antagonists, including warfarin, may have enhanced anticoagulant effects; monitor INR during and shortly after treatment.

Ciprofloxacin may increase exposure to clozapine, ropinirole, sildenafil and other CYP1A2 substrates; appropriate clinical monitoring and dose adjustment may be required.

Concomitant use with other QT-prolonging medicines requires caution.

4.6 Fertility, pregnancy and lactation

Pregnancy

Available human data do not demonstrate malformative or foeto/neonatal toxicity, but because of potential effects on immature cartilage, use during pregnancy should preferably be avoided unless the expected benefit outweighs the risk.

Breast-feeding

Ciprofloxacin is excreted in breast milk and should not be used during breast-feeding because of the potential risk of articular damage.

Fertility

No specific clinically relevant fertility warning is established.

4.7 Effects on ability to drive and use machines

Ciprofloxacin may affect reaction time because of neurological effects. Patients should exercise caution when driving or operating machinery, particularly if dizziness, confusion, tremor, visual disturbance or other neurological effects occur.

4.8 Undesirable effects

The most commonly reported adverse reactions are nausea and diarrhoea.

Common: nausea, diarrhoea.

Uncommon/rare and frequency not known reactions include mycotic superinfection; eosinophilia and other blood dyscrasias; allergic reactions including angioedema and anaphylaxis; appetite or glucose disturbances; agitation, anxiety, confusion, abnormal dreams, depression, hallucinations and psychotic reactions; headache, dizziness, sleep and taste disorders, paraesthesia, tremor and seizures; visual or auditory disturbances; QT prolongation, arrhythmias, hypotension and syncope; vomiting, abdominal pain, dyspepsia and antibiotic-associated colitis; hepatic enzyme changes, hepatitis and hepatic failure; rash, pruritus, urticaria, photosensitivity and severe cutaneous reactions; arthralgia, myalgia, tendinitis and tendon rupture; renal impairment, failure, haematuria and crystalluria; and oedema or sweating.

Prolonged, disabling and potentially irreversible adverse reactions affecting multiple systems have been reported. Aortic aneurysm/dissection and heart-valve regurgitation/incompetence have also been reported.

Suspected adverse reactions should be reported through the applicable national pharmacovigilance reporting system.

4.9 Overdose

Reported overdose has caused dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal/hepatic impairment, crystalluria and haematuria; acute renal failure has been reported after very large doses.

Management is symptomatic and supportive. Monitor renal function and urinary parameters, maintain adequate hydration, consider measures to prevent crystalluria and perform ECG monitoring because of possible QT prolongation. Only a small proportion of ciprofloxacin is removed by haemodialysis or peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Fluoroquinolones. ATC code: J01MA02.

Ciprofloxacin is a bactericidal fluoroquinolone that inhibits bacterial DNA-gyrase (topoisomerase II) and topoisomerase IV, enzymes required for bacterial DNA replication, transcription, repair and recombination.

Resistance may arise through target-site mutations involving DNA gyrase and topoisomerase IV, reduced permeability and/or active efflux. Plasmid-mediated qnr resistance has also been reported. Local susceptibility and resistance data should guide use.

5.2 Pharmacokinetic properties

Absorption: After oral doses of 250–750 mg, ciprofloxacin is rapidly and extensively absorbed, mainly from the small intestine, reaching peak serum concentrations approximately 1–2 hours after administration. Absolute bioavailability is approximately 70–80%.

Distribution: Protein binding is low (approximately 20–30%) and the drug has a large volume of distribution. It achieves therapeutic concentrations in respiratory, sinus, urinary and other tissues.

Metabolism: Several metabolites are formed. Ciprofloxacin is a moderate inhibitor of CYP1A2.

Elimination: Ciprofloxacin is largely excreted unchanged, predominantly through the kidneys and to a lesser extent in faeces. The serum elimination half-life in patients with normal renal function is approximately 4–7 hours. Severe renal impairment can prolong the half-life.

5.3 Preclinical safety data

Non-clinical studies identified no special hazards for humans beyond those described elsewhere in the product information. Ciprofloxacin is phototoxic in animals at clinically relevant exposure levels and can cause cartilage damage in immature weight-bearing joints; mature animals did not show comparable cartilage lesions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (Avicel pH 101)

Colloidal anhydrous silica (Aerosil)

Povidone (PVP)

Corn starch

Magnesium stearate

Macrogol 4000 (PEG 4000)

Titanium dioxide

Hypromellose (hydroxypropylmethyl cellulose)

Methyl paraben

Propyl paraben

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Do not store above 30°C. Store in a cool dry place.

6.5 Nature and contents of container

PVC/Aluminium foil blisters.

Pack size: 1 × 10 caplets.

The blister strips are packed into inner cartons. Ten (10) inner cartons are further packed into a larger intermediate carton, which is then packed into an outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT / HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Cardinal Drugs Limited

14, Ajoke Osho Street, New Oko-Oba, Agege, Lagos, Nigeria.

8. DRUG PRODUCT MANUFACTURER

Cardinal Drugs Limited

14, Ajoke Osho Street, New Oko-Oba, Agege, Lagos, Nigeria.

9. NAFDAC REGISTRATION NUMBER(S)

B4-0795

10. DATE OF REVISION OF THE TEXT

September 2026