SUMMARY OF PRODUCT CHARACTERISTICS
CIPROSTAR-250 (Ciprofloxacin Tablets BP 250 mg)

1. NAME OF THE MEDICINAL PRODUCT

CIPROSTAR-250 (Ciprofloxacin Tablets BP 250 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 250 mg ciprofloxacin hydrochloride BP equivalent to ciprofloxacin.

Excipients with known effect:

This medicinal product does not contain excipients with known effect at the stated dose.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

White coloured, round shaped, biconvex film-coated tablet with a break-line on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Because of the risk of prolonged, disabling and potentially irreversible serious adverse drug reactions, ciprofloxacin must only be prescribed when other antibiotics that are commonly recommended for the infection are inappropriate.

CIPROSTAR-250 is indicated for the treatment of the following infections in adults:

- Lower respiratory tract infections due to Gram-negative bacteria: exacerbations of COPD; broncho-pulmonary infections in cystic fibrosis or bronchiectasis; pneumonia.
- Chronic suppurative otitis media.
- Acute exacerbation of chronic sinusitis (Gram-negative bacteria).
- Urinary tract infections.
- Genital tract infections: gonococcal urethritis/cervicitis; epididymo-orchitis; pelvic inflammatory disease.
- Gastrointestinal tract infections, including travellers' diarrhoea.
- Intra-abdominal infections.
- Skin and soft tissue infections (Gram-negative bacteria).
- Malignant external otitis.
- Infections of bones and joints.
- Prophylaxis of invasive Neisseria meningitidis infections.
- Inhalation anthrax (post-exposure prophylaxis and curative treatment).

In children and adolescents: broncho-pulmonary infections in cystic fibrosis (Pseudomonas aeruginosa); complicated UTIs and pyelonephritis; inhalation anthrax; other severe infections when necessary.

4.2 Posology and method of administration

Adults — Dosage table

Indication	Oral Dose	Duration
Uncomplicated acute cystitis (pre-menopausal women)	250 mg twice daily (or 500 mg single dose)	3 days
Complicated cystitis / acute pyelonephritis	500 mg twice daily	7 days
Bacterial prostatitis	500–750 mg twice daily	2–6 weeks

Indication	Oral Dose	Duration
Lower/upper respiratory tract infections	500–750 mg twice daily	7–14 days
Malignant external otitis	750 mg twice daily	Up to 3 months
Gonococcal urethritis/cervicitis	500 mg single dose	1 day
Epididymo-orchitis / PID	500–750 mg twice daily	At least 14 days
Travellers' diarrhoea / bacterial diarrhoea	500 mg twice daily	1–7 days (depending on pathogen)
Intra-abdominal infections	500–750 mg twice daily	5–14 days
Inhalation anthrax (post-exposure)	500 mg twice daily	60 days

Paediatric population — Dosage table

Indication	Oral Dose	Duration
Cystic fibrosis	20 mg/kg twice daily (max 750 mg/dose)	10–14 days
Complicated UTIs / pyelonephritis	10–20 mg/kg twice daily (max 750 mg/dose)	10–21 days
Inhalation anthrax	10–15 mg/kg twice daily (max 500 mg/dose)	60 days
Other severe infections	20 mg/kg twice daily (max 750 mg/dose)	As indicated

Renal impairment

Creatinine Clearance (ml/min/1.73 m²)	Oral Dose (mg)
>60	See usual dosage
30–60	250–500 mg every 12 hours
<30	250–500 mg every 24 hours
Haemodialysis	250–500 mg every 24 hours (after dialysis)
Peritoneal dialysis	250–500 mg every 24 hours

Method of administration
Tablets to be swallowed unchewed with fluid. Can be taken independent of mealtimes. If taken on an empty stomach, absorption is more rapid. Do not take with dairy products or mineral-fortified fruit juice. Do not take double doses to compensate for a missed dose.

4.3 Contraindications
- Hypersensitivity to ciprofloxacin, other quinolones, or any excipients listed in section 6.1.
- Concomitant administration of ciprofloxacin and tizanidine.

4.4 Special warnings and precautions for use
Serious adverse drug reactions
Because of the risk of prolonged, disabling and potentially irreversible serious adverse drug reactions (including tendinitis/tendon rupture, peripheral neuropathy and CNS effects), ciprofloxacin must only be prescribed when other antibiotics commonly recommended for the infection are inappropriate.

Tendinitis and tendon rupture
Risk is increased in the elderly, patients receiving corticosteroids, and organ transplant patients. If signs of tendinitis occur, ciprofloxacin must be discontinued immediately.

QT prolongation
Like other fluoroquinolones, ciprofloxacin may prolong the QT interval. Caution required with concomitant QT-prolonging drugs, uncorrected electrolyte disturbances, or congenital long QT syndrome.

Peripheral neuropathy
Cases of sensory or sensorimotor peripheral neuropathy have been reported. Ciprofloxacin must be discontinued if symptoms of neuropathy develop.

CNS effects and hepatotoxicity
CNS adverse reactions including dizziness, confusion, tremors, hallucinations and convulsions have been reported. Cases of hepatic necrosis and life-threatening hepatic failure have been reported. Discontinue ciprofloxacin if signs of liver disease develop.

Clostridium difficile
Pseudomembranous colitis has been reported. If suspected, discontinue ciprofloxacin.

4.5 Interaction with other medicinal products and other forms of interaction

Tizanidine:

Contraindicated — causes 7-fold increase in Cmax and 10-fold increase in AUC, associated with hypotension and somnolence.

QT-prolonging drugs:

Caution when co-prescribed with Class IA/III antiarrhythmics, tricyclic antidepressants, macrolides, antipsychotics.

Antacids, sucralfate, minerals:

Significantly reduce ciprofloxacin absorption. Take ciprofloxacin at least 2 hours before or 6 hours after these products.

Dairy products and mineral-fortified drinks:

Avoid concurrent administration as absorption may be reduced.

Theophylline:

Ciprofloxacin inhibits CYP1A2; may increase serum theophylline levels. Monitor theophylline concentrations.

Oral anticoagulants (warfarin):

Enhanced anticoagulant effects reported. Monitor INR closely.

Ciclosporin:

Transient increases in serum creatinine. Monitor twice weekly.

4.6 Fertility, pregnancy and lactation

Pregnancy
As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy. Based on known fluoroquinolone effects on immature cartilage, a risk to the newborn/infant cannot be excluded.

Breast-feeding
Ciprofloxacin is excreted in breast milk. Due to the potential risk of articular damage in breast-fed infants, ciprofloxacin should not be used during breast-feeding.

Fertility
Ciprofloxacin did not impair fertility or produce reproductive toxicity in animal studies.

4.7 Effects on ability to drive and use machines

Due to its neurological effects, ciprofloxacin may affect reaction time. Patients experiencing dizziness, confusion or other CNS adverse reactions should not drive or operate machinery.

4.8 Undesirable effects

Summary of the safety profile
Most commonly reported adverse reactions are nausea, diarrhoea and hepatic enzyme elevations. Serious adverse reactions include tendinitis/tendon rupture, peripheral neuropathy, QT prolongation, hepatic failure and anaphylaxis.

Tabulated list of adverse reactions
Frequencies: common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known.

System Organ Class	Common	Uncommon	Rare / Very Rare / Not Known
Blood and lymphatic		Eosinophilia	Leukopenia, anaemia, neutropenia, thrombocytopenia; agranulocytosis, pancytopenia (life-threatening — very rare)
Immune system			Allergic oedema/angio-oedema; anaphylactic shock (very rare); serum sickness-like reaction
Psychiatric		Psychomotor hyperactivity/agitation	Confusion, depression, hallucinations; psychotic reactions (potentially leading to suicidal ideation — very rare); mania (not known)
Nervous system	Nausea, dizziness	Headache, tremor, somnolence, insomnia	Seizures; peripheral neuropathy/polyneuropathy; SIADH (not known)
Cardiac			QT prolongation, torsades de pointes (not known)
Gastrointestinal	Nausea, diarrhoea	Vomiting, abdominal pain, dyspepsia	Pseudomembranous colitis (rarely life-threatening)
Hepatobiliary	Liver enzyme elevations		Hepatic necrosis — life-threatening hepatic failure (very rare)
Skin disorders		Rash, urticaria, pruritus	SJS, TEN, erythema multiforme; AGEP (not known)
Musculoskeletal		Arthralgia	Tendinitis, tendon rupture; rhabdomyolysis (not known)
Renal and urinary		Renal impairment	Acute renal failure, crystalluria; haematuria (not known)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms include dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment, crystalluria and haematuria. Treatment is symptomatic and supportive. Monitor and protect renal function.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Fluoroquinolones. ATC code: J01MA02.

Mechanism of action: The bactericidal action of ciprofloxacin results from inhibition of both type II topoisomerase (DNA-gyrase) and topoisomerase IV, required for bacterial DNA replication, transcription, repair and recombination. Ciprofloxacin has broad-spectrum activity covering Gram-negative aerobic organisms (including Pseudomonas aeruginosa), Gram-positive organisms and atypical pathogens.

5.2 Pharmacokinetic properties

Absorption: Following oral administration of 250 mg, 500 mg and 750 mg ciprofloxacin tablets, ciprofloxacin is rapidly and extensively absorbed, reaching Cmax within 1–2 hours. Absolute bioavailability approximately 70–80%.

Distribution: Protein binding 20–30%. Apparent volume of distribution 2–3 l/kg. High tissue penetration into lungs, sinuses, inflamed lesions and urogenital tract.

Metabolism: Four metabolites identified at low concentrations (M1–M4) with lower in vitro antimicrobial activity than the parent compound.

Elimination: Primarily excreted unchanged renally. Serum half-life 4–7 hours (normal renal function). Severely impaired renal function extends half-life to up to 12 hours.

5.3 Preclinical safety data

Ciprofloxacin shows genotoxic potential in some in vitro tests with metabolic activation; however, in vivo studies indicate no genotoxic hazard to humans. Not carcinogenic. As with other fluoroquinolones, ciprofloxacin causes arthropathy in immature animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the film-coated tablet:

No.	Ingredient
1	Microcrystalline cellulose
2	Maize starch
3	Purified water
4	Purified talc
5	Magnesium stearate
6	Sodium starch glycolate
7	Colloidal anhydrous silica
8	Film coat (Elegance ELW 1001 white precoat)
9	Titanium dioxide (E171)
10	Isopropyl alcohol
11	Methylene dichloride

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container

10 tablets packed in one ALU-PVC blister; 10 such blisters packed in one carton with package insert. Pack size: 100 tablets.

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. MARKETING AUTHORISATION HOLDER

ZAIN PHARMA LTD.

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P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD11688/25145

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

06.11.2025

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