SUMMARY OF PRODUCT CHARACTERISTICS
CIPROSTAR-500 (Ciprofloxacin Tablets BP 500 mg)

1. NAME OF THE MEDICINAL PRODUCT

CIPROSTAR-500 (Ciprofloxacin Tablets BP 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 500 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, caplet-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, this product must only be prescribed when other antibiotics that are commonly recommended for the infection are inappropriate.

Ciprofloxacin Tablets BP 500 mg are indicated for the treatment of the following infections in adults:

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

Ciprofloxacin may be used in the management of neutropenic patients with fever suspected to be due to a bacterial infection.

Children and adolescents:

- Broncho-pulmonary infections in cystic fibrosis caused by Pseudomonas aeruginosa.
- Complicated urinary tract infections and pyelonephritis.
- Inhalation anthrax (post-exposure prophylaxis and curative treatment).

Ciprofloxacin may also be used to treat severe infections in children and adolescents when this is considered necessary. Treatment should be initiated only by physicians experienced in the treatment of cystic fibrosis and/or severe infections in children and adolescents.

4.2 Posology and method of administration

Posology

The dosage is determined by the indication, the severity and site of the infection, the susceptibility of the causative organism(s), the renal function of the patient, and in children and adolescents the body weight.

Adults — Dosage table:

Indication	Oral Dose	Duration
Lower respiratory tract infections	500–750 mg twice daily	7–14 days
Acute exacerbation of chronic sinusitis / chronic suppurative otitis media	500–750 mg twice daily	7–14 days
Malignant external otitis	750 mg twice daily	28 days up to 3 months
Uncomplicated acute cystitis	250–500 mg twice daily (single dose of 500 mg may be used in pre-menopausal women)	3 days
Complicated cystitis / acute pyelonephritis	500 mg twice daily	7 days
Complicated pyelonephritis	500–750 mg twice daily	At least 10 days (up to >21 days in specific circumstances)
Bacterial prostatitis	500–750 mg twice daily	2–4 weeks (acute); 4–6 weeks (chronic)
Gonococcal urethritis/cervicitis	500 mg single dose	1 day
Epididymo-orchitis / pelvic inflammatory disease	500–750 mg twice daily	At least 14 days
Travellers' diarrhoea / bacterial diarrhoea	500 mg twice daily	1–5 days (depending on pathogen)
Typhoid fever	500 mg twice daily	7 days
Intra-abdominal infections	500–750 mg twice daily	5–14 days
Skin, soft tissue, bone and joint infections	500–750 mg twice daily	7–14 days (skin/soft tissue); 4–8 weeks (bone/joint)
Inhalation anthrax (post-exposure)	500 mg twice daily	60 days

Paediatric population — Dosage table:

Indication	Oral Dose	Duration
Cystic fibrosis	20 mg/kg body weight twice daily (max 750 mg per dose)	10–14 days
Complicated urinary tract infections / pyelonephritis	10–20 mg/kg twice daily (max 750 mg per dose)	10–21 days
Inhalation anthrax (post-exposure)	10–15 mg/kg twice daily (max 500 mg per dose)	60 days
Other severe infections	20 mg/kg twice daily (max 750 mg per dose)	According to type of infection

Elderly patients

Elderly patients should receive a dose selected according to the severity of the infection and the patient's creatinine clearance.

Patients with 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 patients	250–500 mg every 24 hours (after dialysis)

Creatinine Clearance (ml/min/1.73 m²)	Oral Dose (mg)
Peritoneal dialysis patients	250–500 mg every 24 hours

In patients with impaired liver function, no dose adjustment is required.

Method of administration

The tablets are to be swallowed unchewed with fluid. They can be taken independent of mealtimes. If taken on an empty stomach, the active substance is absorbed more rapidly. Ciprofloxacin tablets should not be taken with dairy products (e.g. milk, yoghurt) or mineral-fortified fruit juice. If a dose is missed, it should be taken at any time but not later than 6 hours prior to the next scheduled dose. Double doses should not be taken.

4.3 Contraindications

- Hypersensitivity to the active substance, to other quinolones, or to any of the 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 and tendon rupture, peripheral neuropathy, and central nervous system effects, ciprofloxacin must only be prescribed when other antibiotics commonly recommended for the infection are inappropriate.

Streptococcal infections

Ciprofloxacin is not recommended for the treatment of streptococcal infections due to inadequate efficacy.

Gonorrhoea

Ciprofloxacin should be administered for the treatment of gonococcal urethritis or cervicitis only if ciprofloxacin-resistant Neisseria gonorrhoeae can be excluded.

Tendinitis and tendon rupture

Tendinitis (including Achilles tendon rupture) has been reported with fluoroquinolone use. The risk is increased in the elderly, those receiving corticosteroids, and those with kidney, heart, or lung transplants. If signs or symptoms of tendinitis occur, ciprofloxacin should be discontinued immediately.

QT prolongation

Ciprofloxacin, like other fluoroquinolones, may prolong the QT interval. Caution is required when prescribing ciprofloxacin to patients with known risk factors for QT prolongation, including drugs that prolong QT interval (Class IA and III antiarrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

Peripheral neuropathy

Cases of sensory or sensorimotor peripheral neuropathy resulting in paraesthesiae, hypoaesthesiae, dysaesthesiae and weakness have been reported. Ciprofloxacin should be discontinued if the patient experiences symptoms of neuropathy.

CNS effects

Ciprofloxacin may cause CNS adverse reactions including dizziness, confusion, tremors, hallucinations, and convulsions. Ciprofloxacin should be used with caution in patients with CNS disorders. Convulsions have been reported with quinolone use.

Hepatic impairment

Cases of hepatic necrosis and life-threatening hepatic failure have been reported. If signs and symptoms of liver disease occur, ciprofloxacin should be discontinued.

Clostridium difficile-associated diarrhoea

Pseudomembranous colitis has been reported with ciprofloxacin. If this diagnosis is suspected, ciprofloxacin should be discontinued and appropriate treatment initiated.

Resistance

Treatment with ciprofloxacin may result in overgrowth of non-susceptible organisms. Appropriate measures should be taken if this occurs during therapy.

4.5 Interaction with other medicinal products and other forms of interaction

Tizanidine:

Concomitant administration with tizanidine is contraindicated due to increased plasma concentrations of tizanidine (7-fold increase in Cmax and 10-fold increase in AUC) associated with tizanidine-related adverse reactions such as hypotension and somnolence.

Drugs known to prolong QT interval:

Ciprofloxacin should be used with caution in patients receiving drugs known to prolong QT interval (e.g. Class IA and III antiarrhythmics, tricyclic antidepressants, macrolides, antipsychotics) (see section 4.4).

Antacids, sucralfate, multivitamins, and mineral supplements:

Concomitant administration of ciprofloxacin with antacids containing magnesium, aluminium, or calcium, or products containing iron, zinc, or other minerals significantly reduces ciprofloxacin absorption. Ciprofloxacin should be taken at least 2 hours before or 6 hours after these products.

Food and dairy products:

The concurrent administration of dairy products or mineral-fortified drinks alone with ciprofloxacin should be avoided because absorption may be reduced.

Probenecid:

Probenecid interferes with renal secretion of ciprofloxacin. Co-administration increases ciprofloxacin serum concentrations.

Metoclopramide:

Metoclopramide accelerates the absorption of oral ciprofloxacin, resulting in a shorter time to reach maximum plasma concentrations.

Omeprazole:

Concomitant administration with omeprazole results in a slight reduction of Cmax and AUC of ciprofloxacin.

Theophylline:

Ciprofloxacin inhibits CYP1A2 and may increase serum theophylline concentrations with potential theophylline toxicity. Monitoring of serum theophylline concentrations is recommended during concomitant use.

Cyclosporin:

Ciprofloxacin transiently increases serum creatinine levels when co-administered with ciclosporin. Monitoring of serum creatinine concentrations twice per week is recommended.

Oral anticoagulants (e.g. warfarin, acenocoumarol):

Enhanced anticoagulant effect has been reported. Monitoring of INR is recommended when co-administered.

Methotrexate:

Co-administration may inhibit tubular transport of methotrexate and increase plasma concentrations with potential for enhanced methotrexate-associated toxic reactions. Caution is recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy

As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy. Animal studies with ciprofloxacin do not indicate direct or indirect harmful effects with respect to reproductive toxicity. However, based on the known effects of fluoroquinolones 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 and the potential for other serious adverse reactions, 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 should be cautioned about driving or operating machinery if they experience dizziness, confusion or other CNS adverse reactions.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are nausea, diarrhoea, hepatic enzyme elevations and rash. Serious adverse reactions, including tendinitis/tendon rupture, peripheral neuropathy, QT prolongation, hepatic necrosis, anaphylaxis, and CNS effects, have been reported.

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 (cannot be estimated from the available data).

System Organ Class	Common	Uncommon	Rare	Very Rare / Not Known
Blood and lymphatic disorders		Eosinophilia	Leukopenia, anaemia, neutropenia, leukocytosis, thrombocytopenia	Haemolytic anaemia, agranulocytosis, pancytopenia (life-threatening), bone marrow depression (life-threatening)
Immune system disorders			Allergic reaction, allergic oedema/angio-oedema	Anaphylactic reaction, anaphylactic shock (life-threatening), serum sickness-like reaction
Metabolism disorders		Decreased appetite, hyperglycaemia, hypoglycaemia		
Psychiatric disorders		Psychomotor hyperactivity/agitation	Confusion, disorientation, anxiety, abnormal dreams, depression, hallucinations	Psychotic reactions (potentially progressing to suicidal ideations/attempts); mania
Nervous system disorders	Nausea, dizziness (oral)	Headache, tremor, somnolence, insomnia, taste disturbance	Seizures, peripheral neuropathy/polyneuropathy, paraesthesia, hypoaesthesia	SIADH; intracranial hypertension
Eye disorders			Visual disturbances	
Ear and labyrinth disorders			Tinnitus, hearing loss	
Cardiac disorders			QT prolongation, ventricular arrhythmias (incl. torsades de pointes)	
Vascular disorders			Hypotension, vasodilation, vasodilatation	
Respiratory disorders			Dyspnoea (including asthmatic condition)	
Gastrointestinal disorders	Nausea, diarrhoea	Vomiting, abdominal pain, dyspepsia, flatulence, anorexia	Pseudomembranous colitis (rarely life-threatening)	
Hepatobiliary disorders	Liver enzyme elevations (ALT, AST, ALP)		Hepatic necrosis (very rarely progressing to life-threatening hepatic failure)	Jaundice (cholestatic)
Skin disorders		Rash, urticaria, pruritus, drug hypersensitivity	Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, photosensitivity	Acute generalised exanthematous pustulosis (AGEP)
Musculoskeletal disorders		Arthralgia	Tendinitis, tendon rupture (Achilles), myalgia, muscle weakness	Rhabdomyolysis
Renal and urinary disorders		Renal impairment	Acute renal failure (e.g. due to crystalluria, interstitial nephritis)	Haematuria, crystalluria

System Organ Class	Common	Uncommon	Rare	Very Rare / Not Known
General disorders		Mycotic super-infections		Fever, asthenia

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 of overdosage include dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment, as well as crystalluria and haematuria.

Treatment is symptomatic and supportive. The patient's renal function should be monitored and protected. Haemodialysis or peritoneal dialysis removes only a small (<10%) amount of ciprofloxacin. Antacids containing calcium may reduce absorption of any residual ciprofloxacin still in the gastrointestinal tract.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Fluoroquinolones. ATC code: J01MA02.

Mechanism of action

As a fluoroquinolone antibacterial agent, the bactericidal action of ciprofloxacin results from the inhibition of both type II topoisomerase (DNA-gyrase) and topoisomerase IV, required for bacterial DNA replication, transcription, repair and recombination. Ciprofloxacin has a broad spectrum of antibacterial activity covering Gram-negative aerobic organisms (including Pseudomonas aeruginosa), Gram-positive organisms (including Staphylococcus aureus), and atypical pathogens (Legionella, Chlamydia, Mycoplasma).

5.2 Pharmacokinetic properties

Absorption

Following oral administration of 250 mg, 500 mg, and 750 mg ciprofloxacin tablets, ciprofloxacin is absorbed rapidly and extensively, mainly from the small intestine, reaching maximum serum concentrations 1–2 hours after dosing. The absolute bioavailability is approximately 70–80%.

Distribution

Protein binding of ciprofloxacin is low (20–30%). Ciprofloxacin is present in plasma largely in a non-ionised form and has a large steady-state distribution volume of 2–3 l/kg body weight. Ciprofloxacin reaches high concentrations in tissues including lung, sinuses, inflamed lesions, and the urogenital tract.

Metabolism

Low concentrations of four metabolites have been identified: desethyleneciprofloxacin (M1), sulphociprofloxacin (M2), oxociprofloxacin (M3), and formylciprofloxacin (M4). These metabolites display in vitro antimicrobial activity but to a lower degree than the parent compound.

Elimination

Ciprofloxacin is largely excreted unchanged both renally and, to a smaller extent, faecally. The serum elimination half-life in subjects with normal renal function is approximately 4–7 hours. Renal clearance is between 180–300 ml/kg/h and total body clearance is between 480–600 ml/kg/h. Severely impaired renal function leads to increased half-lives of up to 12 hours.

5.3 Preclinical safety data

Preclinical studies with ciprofloxacin have demonstrated genotoxic potential in some in vitro tests with metabolic activation. However, results from in vivo studies indicate that ciprofloxacin does not represent a genotoxic hazard to humans. Ciprofloxacin is not carcinogenic. Reproductive toxicity studies have shown no adverse effects on fertility. As with other fluoroquinolones, ciprofloxacin causes arthropathy in immature animals; this must be taken into account when prescribing for children.

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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Go-Down No. 1, 2, 3, Off Mombasa Road,
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P.O. Box: 100167-00101, Nairobi, Kenya.

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