Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

CIPROSTAR-500 (Ciprofloxacin Tablets BP 500mg)

2. Qualitative and quantitative composition

Each film coated tablet contains:

Ciprofloxacin Hydrochloride BPEq. to Ciprofloxacin 500mg

3. Pharmaceutical form

Film-coated tablet

4. Clinical particulars

4.1 Therapeutic indications

Ciprofloxacin tablets BP 500 mg film-coated tablets are indicated for the treatment of the following infections.

Adults

- Lower respiratory tract infections due to Gram-negative bacteria
  - exacerbations of chronic obstructive pulmonary disease
  - broncho-pulmonary infections in cystic fibrosis or in bronchiectasis
  - pneumonia
- Chronic suppurative otitis media
- Acute exacerbation of chronic sinusitis especially if these are caused by Gram-negative bacteria
- Urinary tract infections
- Genital tract infections
  - gonococcaluretritis and cervicitis due to susceptible *Neisseria gonorrhoeae*
  - epididymo-orchitis including cases due to susceptible *Neisseria gonorrhoeae*
  - pelvic inflammatory disease including cases due to susceptible *Neisseria gonorrhoeae*
- Infections of the gastro-intestinal 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 that is 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 to be necessary.

Treatment should be initiated only by physicians who are 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 indication, severity and site of the infection, the susceptibility to ciprofloxacin of the causative organism(s), the renal function of the patient and, in children and adolescents the body weight. The duration of treatment depends on the severity of the illness and on the clinical and bacteriological course.

Method of administration

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 mineralfortified fruit-juice (e.g. calcium-fortified orange juice).

4.3 Contraindications

Hypersensitivity to the active substance, to other quinolones or to any of the excipients. Concomitant administration of ciprofloxacin and tizanidine.

4.4 Special warnings and precautions for use

Ciprofloxacin is not recommended for the treatment of streptococcal infections due to inadequate efficacy. Ciprofloxacin should be administered for the treatment of gonococcaluretritis or cervicitis only if ciprofloxacin-resistant Neisseria gonorrhoeae can be excluded.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs known to prolong QT interval: Ciprofloxacin, like other fluoroquinolones, should be used with caution in patients receiving drugs known to prolong QT interval (e.g. Class IA and III anti-arrhythmics, tricyclic antidepressants, macrolides, antipsychotics).

Food and Dairy Products: The concurrent administration of dairy products or mineral fortified drinks alone (e.g. milk, yoghurt, calcium-fortified orange juice)with ciprofloxacin should be avoided because absorption of ciprofloxacin may be reduced.

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

Metoclopramide: Metoclopramide accelerates the absorption of ciprofloxacin (oral) resulting in a shorter time to reach maximum plasma concentrations. No effect was seen on the bioavailability of ciprofloxacin.

Omeprazole: Concomitant administration of ciprofloxacin and omeprazole containing medicinal products results in a slight reduction of Cmax and AUC of ciprofloxacin.

Tizanidine: Because this may cause side effects such as low blood pressure and sleepiness.

4.6 Pregnancy and lactation

Pregnancy: As a precautionary measure, it is preferable to avoid the use of ciprofloxacin during pregnancy.

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

4.7 Effects on ability to drive and use machines

Due to its neurological effects, ciprofloxacin may affect reaction time. Thus, the ability to drive or to operate machinery may be impaired.

4.8 Undesirable effects

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.

Uncommon: Mycotic super-infections, Eosinophilia, Decreased appetite, Psychomotor hyperactivity/ agitation;

Rare: Leukopenia, Anaemia, Neutropenia, Leukocytosis, Thrombocytopenia, Thrombocytaemia, Allergic reaction, Allergic oedema / angiooedema, Hyperglycaemia, Hypoglycaemia, Confusion and disorientation, Anxiety, Abnormal dreams, Depression, Hallucinations;

Very Rare: Haemolyticanaemia, Agranulocytosis, Pancytopenia (life-threatening), Bone marrow depression (life-threatening), Anaphylactic reaction, Anaphylactic shock (lifethreatening), Serum

sickness-like reaction, Psychotic reactions (potentially culminating in suicidal ideations/ thoughts or suicide attempts and completed suicide);

Frequency not known: Syndrome of inappropriate secretion of antidiuretic hormone (SIADH), Mania,

4.9 Overdose

Symptoms in overdose consist of dizziness, tremor, headache, tiredness, seizures, hallucinations, confusion, abdominal discomfort, renal and hepatic impairment as well as crystalluria and haematuria.

5.0 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.

5.2 Pharmacokinetic properties

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

Distribution: Protein binding of ciprofloxacin is low (20-30%). Ciprofloxacin is present in plasma largely in a nonionised form and has a large steady state distribution volume of 2-3 l/kg body weight. Ciprofloxacin reaches high concentrations in a variety of tissues such as lung (epithelial fluid, alveolar macrophages, biopsy tissue), sinuses, inflamed lesions (cantharides blister fluid), and the urogenital tract (urine, prostate, endometrium) where total concentrations exceeding those of plasma concentrations are reached.

Metabolism: Low concentrations of four metabolites have been reported, which were identified as: desethyleneciprofloxacin (M1), sulphociprofloxacin (M2), oxociprofloxacin (M3) and formylciprofloxacin (M4). The 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 the total body clearance is between 480-600 mL/kg/h.

Ciprofloxacin undergoes both glomerular filtration and tubular secretion. Severely impaired renal function leads to increased half-lives of ciprofloxacin of up to 12 h. Non-renal clearance of ciprofloxacin is mainly due to active trans-intestinal secretion and metabolism. 1% of the dose is excreted via the biliary route. Ciprofloxacin is present in the bile in high concentrations.

5.3 Preclinical safety data

Not found.

6.Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Name of Excipient	Specification
1	Microcrystalline cellulose	BP
2	Maize Starch	BP
3	Purified water	BP
4	Purified Talc	BP
5	Magnesium Stearate	BP
6	Sodium Starch Glycolate	BP
7	Colloidal Anhydrous Silica	BP
8	Elegance ELW 1001-white precoa	IH
9	Titanium Di- oxide	BP
10	Iso Propyl Alcohol	BP
11	Methylene dichloride	BP

6.1 Incompatibilities

None known

6.2 Shelf life

36 months

6.3 Special precautions for storage

Store in a cool, dry place at temperature not exceeding 30°C. Protect from light.

6.4 Nature and contents of container

10 tablets are packed in ALU-PVC blister, such 10 blisters are packed in one carton with insert coded with batch number, manufacturing date and expiry date.

6.5 Special precautions for disposal and other handling

Not applicable

7. Marketing Authorisation Holder

ZAIN PHARMA LTD.

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8. Marketing Authorization Number

H2025/CTD12277/25040

9. Date of first authorization/renewal of the authorization

2025 November 03

10. Date of revision of the text

2025 November 03