Summary of Product Characteristics (SPC)

1.Name of Medicinal Product

Product Name: Ciproquin-500 (Ciprofloxacin Tablets USP 500mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains
Ciprofloxacin Hydrochloride USP
Equivalent to Ciprofloxacin……
500mg Excipients… Q.S

For the full list of excipients, Refer the Section 6.1

3.PHARMACEUTICAL FORM

Tablets (oral)
CIPROQUIN 500mg White colored, capsule shaped film coated tablets, plain on one side and breakline on other side without any visible defects.

4.CLINICAL PARTICULARS

4.1 Therapeutic indications:

For the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below:
Lower respiratory infections, Skin & skin structure infections, Bone and joint infections, Urinary tract infections and infections diarrhea caused by E.Coli (enterotoxigenic strains), Campylobacter jejuni, Shigella Flexneri and Shigella sonnel when antibacterial therapy is indicated. Inhalation anthrax (post-exposure prophylaxis and curative treatment)

4.2 Posology and method of administration:

Posology

Urinary tract infections: 250mg. every 12 hours.
Complicated infections caused by organisms not highly susceptible: 500mg. every 12 hours.
Respiratory tract infections, skin and skin structure infections and bone and joint infections; 500mg, every 12 hours. More severe or complicated

infections: 750mg. Every 12 hours.

Infectious diarrhea: 500 mg. every 12 hours. The duration of treatment depends upon the severity of infection. Generally, continue ciprofloxacin for atleast 2 days after the signs and symptoms of infection have disappeared. The usual duration is 7 to 14 days; however, for severe and complicated infections, more prolonged therapy may be required. Bone and joint infections may require treatment for 4 to 6 week or longer. Infectious diarrhoea may be treated for 5 to 7 days.

The need for liberal water intake during Ciprofloxacin therapy should be impressed upon the patients. In elderly patient who have difficulty in swallowing it is recommended to commence therapy with intravenous ciprofloxacin until a switch to oral administration is possible

Method of administration

Tablet for Oral administration

4.3 Contraindications:

Hypersensitivity to Ciprofloxacin or any other Quinolones is a contraindication to its use. Children below 12 years should not be put on Ciprofloxacin Therapy. Concomitant administration of ciprofloxacin and tizanidine.

4.4 Special warnings and precautions for use:

CNS stimulation may occur with ciprofloxacin, as with other quinolones, which may lead to tremor, restlessness, light-headedness, confusion and very rarely to hallucinations or convulsive seizures. Use with caution in patients with known or suspected CNS disorders, such as severe cerebral arteriosclerosis or epilepsy, or other factors which predispose to seizures. Crystalluria related to ciprofloxacin has been reported only rarely in man because human urine is usually acidic. Patients receiving ciprofloxacin should be well hydrated and should avoid alkalinity of the urine. Do not exceed the recommended daily dose.

Superinfection: Use of antibiotics (especially prolonged or repeated therapy) may result in bacterial or fungal overgrowth of nonsusceptible organisms.

Such overgrowth may lead to a secondary infection. Appropriate measures

if superinfection occurs.

Tendinitis: At any sign of tendinitis (e. g. painful swelling) the administration of Ciprofloxacin should be discontinued, physical exercises be avoided, and a physician consulted. Avoid use in patient on corticosteroids therapy due to risk of tendinitis and tendon rupture especially in elderly patient.

Ciprofloxacin may exacerbate the clinical symptoms of myasthenia gravis like pain, weakness or swelling specially in arms and legs, change in vision, taste or hearing.

Dose adjustment is required in patients with renal impairment especially and elderly patients as Ciprofloxacin is excreted mainly by kidneys.

Ciprofloxacin should be discontinued if the patient experiences symptoms of neuropathy (pain, feel pins and needles, tingling, tinkling, and numbeness) in order to prevent the development of an irreversible condition

4.5 Interactions with other medicinal products and other forms of interactions Ciprofloxacin absorption is significantly reduced when iron salts, or magnesium- calcium- or aluminium-containing antacids are administered concomitantly. Antacids should not be taken 2 hours before or after Ciprofloxacin tablet administration.

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

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.

Tizanidine serum concentrations were remarkably increased when administered with ciprofloxacin. Increased serum tizanidine concentration is associated with a potentiated hypotensive and sedative effect.

A transient rise in the concentration of serum creatinine was observed when ciprofloxacin and cyclosporin containing medicinal products were administered simultaneously. Serum creatinine concentrations should be monitored.

Increased coagulation tests (PT/INR) and/or bleeding, which may be

severe, have been reported in patients treated with ciprofloxacin in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests, therefore, should be monitored in patients treated with vitamin K antagonists

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

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

Serum concentrations of methotrexate, theophylline, xanthine derivatives, phenytoin, duloxetine, ropinirole, lidocaine, sildena□l, agomelatine, zolpidem and clozapine were found to be increased upon co-administration with ciprofloxacin. Concomitant therapy should be avoided.

4.6 Fertility, Pregnancy and lactation

Usage in Pregnancy: Category C. Since ciprofloxacin, like other drugs in its class, causes arthropathy in immature animals, it should not be used in pregnant women.

Usage in Lactation: It is unknown whether ciprofloxacin is excreted in human milk, however, ciprofloxacin is excreted in the milk of lactating rats, and other drugs of this class are excreted in human milk. Because of the potential for serious adverse effects from ciprofloxacin in nursing infants, decide whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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

Ciprofloxacin is generally well tolerated. Most frequent adverse effects are nausea, diarrhoea, vomiting, abdominal discomfort, headache, restlessness and rash. Other effects are GI effects, CNS, Skin / Hypersensitivity, Special Senses like blurred vision, disturbed vision (change in colour, perception , over brightness of lights), decreased visual

acuity, diplopia, eye pain, tinnitus, bad taste, Musculloskeletal, Renal/Urogenital disorders , arthralgia, myalgia, peripheral neuropathy, hallucinations, anxiety, depression , insomnia, confusion, hypoglycemia, photo-sensitivity).

These reactions may occur within a few hours to several weeks after using the drug. Patients at any age or without pre-existing risk factors may experience these adverse reactions.

Stop using the drug as soon as the first signs or symptoms of any serious adverse reactions occur and consult your physician.

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org ’

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. Reversible renal toxicity has been reported.

Apart from routine emergency measures, e.g. ventricular emptying followed by medical carbon, it is recommended to monitor renal function, including urinary pH and acidify, if required, to prevent crystalluria. Patients should be kept well hydrated. Calcium or magnesium containing antacids may theoretically reduce the absorption of ciprofloxacin in overdoses

Only a small quantity of ciprofloxacin (<10%) is eliminated by haemodialysis or peritoneal dialysis. In the event of overdose, symptomatic treatment should be implemented. ECG monitoring should be undertaken, because of the possibility of QT interval prolongation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ciprofloxacin is a fluorinated quinoline, with potent in vitro antibacterial activity against most antibacterial species. The primary mechanism of action of ciprofloxacin and other quinolones involve inhibition of bacterial DNA gyrase Enzyme required for DNA replication, transcription, repair, and recombination. Ciprofloxacin is bactericidal at concentration equal or

slightly greater than inhibitory concentration. In general, against Gram-negative aerobes in vitro,

The antibacterial activity of Ciprofloxacin is influenced little, if at all, by inoculum size, growth medium or the presence of serum.

5.2 Pharmacokinetic properties

Oral administration of single dose 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% Protein binding of ciprofloxacin is low (20-30%).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. Low concentrations of four metabolite have been reported, which were identified as: desethyleneciprofloxacin (M 1), sulphociprofloxacin (M 2), oxociprofloxacin (M 3) and formylciprofloxacin (M 4). The metabolites display in-vitro antimicrobial activity but to a lower degree than the parent compound. Ciprofloxacin is known to be a moderate inhibitor of the CYP 450 1A2 iso-enzymes. 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. Ciprofloxacin undergoes both glomerular filtration and tubular secretion. Severely impaired renal function leads to increased half-lives of ciprofloxacin of up to 12 h. If eGFR 30-60 ml/ minute/1.73 m2 (every 24 hours if eGFR less than 30 ml/ minute/1.73 m2.

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

5.3 Preclinical safety data

No Preclinical data has been supplied with this application and none are required for applications of this type.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Sodium Starch
Glycollate Magnesium
stearate Colloidal
Anhydrous Silica
Wincoat WT-1001
White/

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months (3 Years)
Proposed shelf life (after first opening container):
NA Proposed shelf life (after reconstitution or
dilution): NA

6.4 Special precautions for storage

Store below 30°C in a dry place. Protect from moisture.

6.5 Nature and contents of container

Alu/PVC blister pack of 10×10 tablets

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER:

KOPRAN LIMITED,
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8. Marketing authorization registration number(s).

10870

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

20/01/2026

10. DATE OF REVISION OF THE TEXT:

20/01/2026