

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Brand Name: CIPROKANT-500

Generic Name: Ciprofloxacin Tablets USP 500mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:

Ciprofloxacin Hydrochloride USP

Equivalent to Ciprofloxacin.....500 mg

Excipients.....q.s.

Colour: Titanium Dioxide

3. PHARMACEUTICAL FORM

Oral, Solid Dosage Form-Tablets

White, film coated, oval shaped tablets having one side break line and “500” debossed on other side of the tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Ciprofloxacin Tablets 500 mg is indicated for the treatment of a wide variety of infections caused by susceptible gram-positive and gram-negative organisms including mixed infections caused by two or more organisms. It may also be used for infections caused by multi-drug resistant bacteria. Ciprofloxacin Tablets 500 mg is indicated for the treatment of the following infections caused by susceptible bacteria:

Respiratory Tract Infections: Acute and chronic bronchitis, obstructive airways disease (COPD) , empyema , lungabscess , bronchiectasis, lobar and bronchopneumonia, acute exacerbation of cystic fibrosis, otitis media, sinusitis and mastoiditis especially due to gram-negative bacteria (including Pseudomonas sp.)

Urinary Tract Infections: Acute and chronic pyelonephritis, cystitis, urethritis, prostatitis, epididymitis and chronic complicated or recurrent UTI caused by multi-drug resistant organisms and/or Pseudomonas aeruginosa.

Skin and Soft Tissue Infections: In surgical and post-operative wound infections due to gram - negative organisms such as Pseudomonas aeruginosa. Also useful in infections caused by

resistant Staphylococci including infected ulcers, wound infections, abscesses, cellulitis, erysipelas, infected burns.

Surgical Infections: Peritonitis, intra - abdominal abscess, cholecystitis, empyema of gall bladder, cholangitis.

Bone And Joint Infections: Acute and chronic osteomyelitis, septic arthritis.

Pelvic Infections: Salpingitis, endometritis, pelvic inflammatory disease.

Sexually Transmitted Diseases: Gonorrhoea including that caused by betalactamase producing strains and chancroid caused by H. ducreyi.

Gastrointestinal Infections: Enteric fever, infective diarrhoea.

Severe Systemic Infections: Septicaemia, bacteraemia, infections in immunocompromised patients.

4.2. Posology and method of administration:

Ciprofloxacin Tablets 500 mg should be swallowed whole with adequate amount of liquid. Ciprofloxacin tablets can be taken without regard to meals. Fluids should be taken liberally. Antacids should not be taken concomitantly or within two hours of dosing.

Adults: Respiratory tract, bone and joint infections :

Mild/Moderate 500 mg twice daily.

Severe/Complicated 750 mg twice daily.

Urinary tract infections : Mild/moderate 250 mg twice daily. Severe/complicated 500 mg twice daily.

Infectious diarrhoea : Mild/moderate/severe 500 mg twice daily.

Gonorrhoea : 500 mg single dose.

Non-gonococcal urethritis : 750 mg twice daily.

Chancroid : 500 mg twice daily.

Other infections : 500-750 mg twice daily

4.3. Contraindications:

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

4.4. Warning and precautions for use

Paediatric use: As with other drugs of this class, ciprofloxacin has been shown to cause arthropathy in weight-bearing joints of immature animals. Hence ciprofloxacin is usually not recommended for use in children.

However, if benefits are considered to outweigh the potential risk, it may be administered.

In impaired renal damage : Dosage adjustments will be required in patients with moderate to severe impairment of renal function. Monitoring of serum drug levels is the most reliable basis for dosage adjustment.

If creatinine clearance is less than 20 ml/min, half the recommended dosage may be administered.

Others:

CNS stimulation: As ciprofloxacin may cause CNS stimulation, it should be used with Caution in patients with CNS disorders such as severe cerebral arteriosclerosis or epilepsy.

Crystalluria: Inadequate intake of water, when on ciprofloxacin, can cause crystalluria.

Phototoxicity : Moderate to severe phototoxicity manifested by an exaggerated sunburn reaction has been observed in patients who are exposed to direct sunlight with some members of the quinolone class of drugs.

Therapy should be discontinued if phototoxicity occurs.

4.5. Drug Interactions

Theophylline: Serum concentrations and elimination half-life of theophylline may be increased when it is used concurrently with ciprofloxacin. Theophylline doses should be reduced and plasma levels monitored.

Antacids: Antacids containing magnesium hydroxide and/or aluminium hydroxide may interfere with the absorption of ciprofloxacin, resulting in lower serum and urine levels; concurrent administration of antacids with ciprofloxacin should be avoided.

Anticoagulants: Prolongation of bleeding time has been reported during concomitant administration of ciprofloxacin and anticoagulants.

Cyclosporin: Transient increases in serum creatinine have been seen following concomitant

administration of cyclosporin and ciprofloxacin.

Caffeine: Ciprofloxacin may interfere with the metabolism of caffeine, resulting in reduced clearance of caffeine.

4.6. Pregnancy & Lactation

PREGNANCY:

The data that are available on administration of ciprofloxacin to pregnant women indicates no malformative or feto/neonatal toxicity of ciprofloxacin. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. In juvenile and prenatal animals exposed to quinolones, effects on immature cartilage have been observed thus, it cannot be excluded that the drug could cause damage to articular cartilage in the human immature organism / foetus

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 breastfeeding.

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.Adverse Effects

Ciprofloxacin is generally well tolerated.

Diarrhoea, vomiting, abdominal pain, headache, restlessness and rash, have been reported. Other side effects which have been reported very rarely include myalgia, tendinitis/rupture, exacerbation of myasthenia gravis and increases in serum transaminase levels.

Potentially life-threatening effects : A series of 15 cases of anaphylactoid reactions has been reported associated with ciprofloxacin.

Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic failure have been reported rarely.

Severe or irreversible effects: As with all quinolones, seizures may occur and this effect may be potentiated by concurrent use of nonsteroidal anti-inflammatory drugs .

Pseudomembranous colitis has occurred with ciprofloxacin therapy.

Transient disturbance of hearing has been reported, particularly during high-dose therapy.

Symptomatic adverse effects: Probable or possible drug-related reactions were reported in 93% of 9473 patients treated with ciprofloxacin worldwide. The incidence of severe reactions was 0.6%. The most frequent reactions were from the gastro intestinal system(nausea,diarrhea,vomiting,dyspepsia),central nervous system(dizziness, headache, nervousness, tremors, seizures, confusion) and skin (rash, pruritus, urticaria, photosensitivity).

Other effects: Elevation of AST (SGOT) and ALT (SGPT), blood creatinine, and blood urea have been observed. Eosinophilia, leucopenia and thrombocytopenia have also been related to ciprofloxacin use.

Interference with clinical pathology tests:No technical interferences of this kind have been reported.

4.9.Overdose

An overdose of 12g has been reported to lead to mild symptoms of toxicity. An acute overdose of 16g has been reported to cause acute renal failure.

Symptoms of overdose may include dizziness,tremor, headaches, 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:

Pharmacotherapeutic group: Fluoroquinolones

Mechanism of Action:

As a fluoroquinolones 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.

Single doses of 100-750 mg produced dose dependent maximum serum concentrations (C_{max}) between 0.56 and 3.7 mg/L. Serum concentration increase proportionately with doses up to 1000 mg.

The absolute bioavailability is approximately 70 – 80%.

A 500 mg oral dose given every 12 hours has been shown to produce an area under the serum concentration-time curve (AUC) equivalent to that produced by an intravenous infusion of 400mg ciprofloxacin given over 60 minutes every 12 hours.

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 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.

Biotransformation

Low concentrations of four metabolites 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 isoenzymes.

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.

6. PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Microcrystalline Cellulose, Maize Starch, Purified Water, Magnesium Stearate, Colloidal Anhydrous Silica, Stearic Acid, Sodium Starch Glycolate, Wincoat White, Isopropyl alcohol, Dichloromethane.

6.2.Incompatibilities

Not Applicable

6.3.Shelf Life

36 Months

6.4.Special precautions for storage:

Do not store above 30°C. Protect from light.

Keep the medicine out of reach of children.

6.5.Nature and contents of container

10 tablets in a blister. Such 10 blisters in carton alongwith insert.

6.6.Special precautions for disposal and other handling

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

7. MARKETING AUTHORISATION HOLDER:

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8. NATIONAL REGISTRATION NUMBER

07573/08438/REN/2022

9. DATE OF AUTHORISATION

01/08/2022

10. DATE OF REVISION OF THE TEXT

30/08/2019