

Patient Information Leaflet

Ciprofloxacin Tablets USP 500mg - CIPROKANT-500

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
 - If you get any side effects, talk to your doctor or pharmacist.
- This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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1.What Ciprokant is and what it is used for

Ciprofloxacin is an antibiotic belonging to the fluoroquinolone family.

The active substance is ciprofloxacin. Ciprofloxacin works by killing bacteria that cause infections. It only works with specific strains of bacteria.

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.

2. What you need to know before you take Ciprokant

Do not take Ciprofloxacin:

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

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.

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.

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.

3.How to take Ciprokant

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.Possible side 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.

Symtomatic 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.

5. How to store Ciprokant

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

Keep the medicine out of reach of children.

6. Contents of the pack and other information

Ciprofloxacin film-coated tablets are available in PVC-Aluminum foil blister pack.

Pack sizes: 10x10 Alu-PVC Blister pack

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