

Ciprofloxacin Injection USP (0.2% w/v)

Ciprox™

For I.V. use only.

Composition

Each 100 ml contains:
Ciprofloxacin USP 200 mg
Sodium Chloride BP 900 mg
Water for Injections BP q.s.
mOsmol/L : 314
mmol/L : Na⁺ 154, Cl⁻ 154

Mechanism of Action

Ciprox™ exerts a potent bactericidal effect by inhibition of the a subunit of DNA gyrase, an essential enzyme involved in DNA replication, precipitating a sequence of events leading to death of the bacteria.

Antimicrobial Activity

Gram-Negative Organisms

Enterobacteriaceae including *E. coli*, *Salmonella* species, *Klebsiella* species, *Shigella*, *Proteus mirabilis*, *Proteus vulgaris*, *K. oxytoca*, *Yersinia enterocolitica*, *Enterobacter*, *Citrobacter*, *Morganella morganii*.

Pseudomonas aeruginosa, *Haemophilus influenzae*, *Acinetobacter*, *Campylobacter*, *Brucella melitensis*, *Pasteurella multocida*, *Eikenella corrodens*, *Flavobacterium*, *Moraxella*, *Gardnerella vaginalis*, *Legionella* species, *Vibrio cholerae* and *Vibrio parahaemolyticus*, *Neisseria meningitidis* and *Neisseria gonorrhoeae* including β -lactamase producing strains.

Gram-Positive Organisms

Staphylococcus aureus including β -lactamase producing and methicillin-resistant strains, *Streptococcus pneumoniae*, group A β -hemolytic *Streptococci*, group B *Streptococci* and other *Streptococci*, *Enterococci* including *Enterococcus faecalis*, *Corynebacterium* and *Listeria monocytogenes*.

Other Organisms

Anaerobic bacteria including *Actinomyces*, *Bifidobacterium*, *Peptococcus*, *Clostridium perfringens*, *Eubacterium*, *Propionibacterium acnes*, *Veillonella* and some strains of *Bacteroides*, *Chlamydia*, *Mycoplasma* and *Mycobacterium*.

Ciprox™ is effective against organisms resistant to nalidixic acid. Since cross resistance is unlikely, **Ciprox™** may be used to treat infections caused by organisms resistant to other class of antibacterials such as aminoglycosides, penicillins, sulfonamides, tetracyclines and cephalosporins.

Indications

Ciprox™ 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.

The potent broad-spectrum antibacterial activity of **Ciprox™** (including activity against *Pseudomonas*) combined with its excellent tissue penetration, enables **Ciprox™** to be used alone effectively pending sensitivity results. However, to provide an effective coverage against anaerobes it may be combined with metronidazole, where presence of anaerobes is suspected.

Ciprox™ is indicated for the treatment of the following infections caused by susceptible bacteria:

RESPIRATORY TRACT INFECTIONS: Acute bronchitis, exacerbation of chronic obstructive airways disease, empyema, lung abscess, infected bronchiectasis, cystic fibrosis and pneumonia.

URINARY TRACT INFECTIONS: Acute and chronic pyelonephritis, prostatitis, cystitis, epididymitis and chronic complicated or recurrent UTI caused by multi-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 *Enterobacteriaceae* and *pseudomonas aeruginosa*. Also useful in infections caused by resistant *Staphylococci*.

SURGICAL INFECTIONS: Peritonitis, intra-abdominal abscess, cholangitis, cholecystitis, empyema of gall bladder.

BONE AND JOINT INFECTIONS: Since **Ciprox™** achieves adequate tissue concentrations in bone, it is useful in the management of acute and chronic osteomyelitis.

GYNAECOLOGICAL INFECTIONS: Severe pelvic infections caused by susceptible bacteria.

SEXUALLY TRANSMITTED DISEASES: Gonorrhoea including that caused by beta-lactamase producing strains, chancroid caused by *H. ducreyi*.

GASTROINTESTINAL INFECTIONS: Effective in the treatment of typhoid and in the eradication of carrier stage. Useful in resistant *Salmonella typhi* infections.

SEVERE SYSTEMIC INFECTIONS: Septicaemia, bacteremia, infections in immunocompromised patients.

Contraindications

Ciprofloxacin is contraindicated in individuals with a history of hypersensitivity to ciprofloxacin or any other quinolone derivative. Its use is not recommended in children below the age of 12 years.

Precautions

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

Patients receiving this drug should be well hydrated to prevent crystalluria.

Excessive alkalization of urine should be avoided. The dosage should be reduced in patients with renal impairment.

Antacids containing magnesium hydroxide and/or aluminium hydroxide may interfere with the absorption of ciprofloxacin.

Concurrent administration of antacids with ciprofloxacin should be avoided.

Production studies in animals at doses 6 times the usual daily human dose have not revealed any evidence of

impaired fertility or teratogenicity due to **Ciprox™**. However, information from well controlled studies in pregnant women is not available. Since **Ciprox™** causes arthropathy in immature animals, it should not be used in pregnant and nursing women.

Drug Interactions

Serum concentrations and elimination half-life of theophylline may be increased when it is used concurrently with ciprofloxacin. It is recommended that patients be monitored for the signs of theophylline toxicity during concurrent use and dosage adjustments made as appropriate. Probenecid delays excretion of ciprofloxacin.

Adverse Reactions

Ciprofloxacin is generally well tolerated. During clinical trials in a large number of patients, adverse effects related to the drug occurred infrequently and were commonly reported as diarrhoea, vomiting, abdominal pain, headache, restlessness and rash.

Other side effects which have been reported very rarely include local irritation at the site of injection, thrombophlebitis, convulsions, anthralgia and increases in serum transaminases.

Dosage and Administration

The dosage of intravenous **Ciprox™** is determined on the basis of severity of infections, type of infecting organisms and age, weight and renal function of the patient.

Upper and lower UTI-100-200 mg twice daily by slow IV infusion.

Lower Respiratory Tract Infections -200 mg twice daily by slow IV infusion.

In majority of other infections, 200 mg should be administered by slow IV infusion every 12 hours.

Children

Ciprofloxacin is usually not recommended for use in children. However, if the benefits of ciprofloxacin therapy are considered to outweigh the potential risk, the dosage should be 5-10 mg/kg/day in two divided doses, depending on the severity of the infection.

Administration

Ciprox™ may be infused directly and should be administered by short term infusion over periods of 30 -60 minutes, preferably through larger veins.

Ciprox™ is compatible with physiological saline solution, Ringer's solution, 5% and 10% dextrose solution/saline and 10% fructose solution.

Caution: Not to be used if container is found leaking or solution is not clear.

Solutions containing visible solid particles must not be used. Discard any unused portion of the contents.

Duration of Therapy

The duration of **Ciprox™** therapy depends upon the type and severity of the infection and should be determined by clinical and bacteriological response of the patient.

For most infections, therapy should be continued for at least 48 hours after the patient becomes asymptomatic. The usual duration is 1-2 weeks, but severe or complicated infections may require more prolonged therapy.

Intravenous therapy should be replaced by oral tablets at the appropriate time.

Renal Impairment

Dosage adjustments will be required in patients with moderate to severe impairment of renal function.

In patients with severe renal impairment (creatinine clearance less than 20 ml/minute) the total daily dose may be reduced by half.

Presentation

Ciprox™ is available in 100 ml Glass container.

Storage Precaution

Store below 30°C, protected from light. Do not freeze.

THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription, without consulting your Doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

Claris

Manufactured by :

Claris Lifesciences Limited

Chacharwadi-Vasana,
Ahmedabad-382 213, India.