

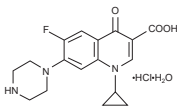
DIPRO

(Ciprofloxacin)

250mg & 500mg Tablets U.S.P.
For Oral Suspension U.S.P.
125mg/5ml & 250mg/5ml
I.V. Infusion B.P. 200mg / 100ml

DESCRIPTION:

DIPRO is a fluoroquinolone antibacterial, active against gram positive and gram negative bacteria. It is available as monohydrate salt of 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinoline-carboxylic acid.



WARNING:

Fluoroquinolones, including DIPRO, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Fluoroquinolones, including DIPRO, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid DIPRO in patients with known history of myasthenia gravis.

COMPOSITION:

DIPRO 250mg Tablets, U.S.P.: Each film-coated tablet contains:

Ciprofloxacin HCl U.S.P. eq. to Ciprofloxacin250mg

DIPRO 500mg Tablets, U.S.P.: Each film-coated tablet contains: Ciprofloxacin HCl U.S.P. eq. to Ciprofloxacin500mg

DIPRO For Oral Suspension U.S.P. 125mg/5ml: Each 5ml of reconstituted suspension contains: Ciprofloxacin (as HCl) taste masked micro pellets125mg

DIPRO For Oral Suspension U.S.P. 250mg/5ml: Each 5ml of reconstituted suspension contains: Ciprofloxacin (as HCl) taste masked micro pellets250mg

DIPRO Infusion 200mg/100ml B.P.: Each 100ml contains:

Ciprofloxacin Lactate Eq. to Ciprofloxacin ...200mg

Each ml of solution for infusion contains:

Ciprofloxacin Lactate Eq. to Ciprofloxacin ...2mg

MICROBIOLOGY:

Gram-positive bacteria

Staphylococcus epidermidis
Staphylococcus haemolyticus
Streptococcus anginosus
Streptococcus milleri
Streptococcus mitis
Streptococcus pneumoniae
Streptococcus pyogenes

Gram-negative bacteria

Escherichia coli
Haemophilus influenzae
Haemophilus parainfluenzae
Klebsiella spp.
Legionella spp.

Gram-positive aerobes

Moraxella catarrhalis
Neisseria gonorrhoeae
Neisseria meningitidis
Proteus mirabilis
Pseudomonas aeruginosa
Salmonella spp.
Salmonella typhi
Shigella spp.
Vibrio spp.

Gram-negative aerobes

Aeromonas hydrophila
Aeromonas caviae
Aeromonas salmonicida
Aeromonas sobria
Aeromonas hydrophila
Aeromonas caviae
Aeromonas salmonicida
Aeromonas sobria

Gram-negative bacteria

Acinetobacter baumannii
Acinetobacter lwoffii
Acinetobacter antrax
Acinetobacter baumannii
Acinetobacter lwoffii
Acinetobacter antrax
Acinetobacter baumannii
Acinetobacter lwoffii
Acinetobacter antrax

Gram-negative bacteria

Chlamydia spp.
Mycobacterium fortuitum
Mycobacterium tuberculosis
Mycobacterium avium
Mycobacterium goodii
Mycobacterium mageritense
Mycobacterium neoaurum
Mycobacterium neoaurum
Mycobacterium neoaurum

Gram-negative bacteria

Mycobacterium fortuitum
Mycobacterium tuberculosis
Mycobacterium avium
Mycobacterium goodii
Mycobacterium mageritense
Mycobacterium neoaurum
Mycobacterium neoaurum
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Mycobacterium fortuitum
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interference with DNA function. Ciprofloxacin is highly active against a wide range of Gram-positive and Gram-negative organisms.

PHARMACOKINETICS: Absorption: Absorption of oral doses of ciprofloxacin tablet formulation occurs rapidly, mainly from the small intestine. Plasma levels are dose related and peak 0.5-2.0 hours after dosing. The AUC also increases dose proportionately after administration of both single and repeated oral (tablet) and intravenous doses. The absolute bioavailability is reported to be 52-83% and ciprofloxacin is subject to only slight first pass metabolism. The oral bioavailability is approximately 70-80%. The intake of food at the same time as administration of oral ciprofloxacin has a marginal but clinically not relevant effect on the pharmacokinetic parameters Cmax and AUC. **DISTRIBUTION:** Distribution of ciprofloxacin within tissues is wide and the volume of distribution high, though slightly lower in the elderly. Protein binding is low (between 19-40%). **ELIMINATION:** Elimination of ciprofloxacin and its metabolites occurs rapidly, primarily by the kidney. After single oral and intravenous doses of ciprofloxacin, 55% and 75% respectively are eliminated by the kidney and 39% and 14% in the faeces within 5 days.

THERAPEUTIC INDICATIONS:

Respiratory Tract Infections: Lobar and bronchopneumonia, acute exacerbation of cystic fibrosis, bronchiectasis, emphysema, Gram-negative pneumonia. **Ear, nose and throat infections:** Mastoiditis, otitis media and sinusitis, especially if due to Gram-negative bacteria (including *Pseudomonas* spp.). **Urinary tract infections:** Uncomplicated and complicated urethritis, cystitis, pyelonephritis, prostatitis, epididymitis. **Skin and soft tissue infections:** Infected ulcers, wound infections, abscesses, cellulitis, otitis externa, erysipelas, infected burns. **Bone and joint infections:** Osteomyelitis, septic arthritis. **Intra-abdominal infections:** Peritonitis, intra-abdominal abscesses. **Infections of the biliary tract:** Cholangitis, cholecystitis, emphysema of the gall bladder. **Gastro-intestinal infections:** Enteric fever, infective diarrhoea. **Pelvic infections:** Salpingitis, endometritis, pelvic inflammatory disease. **Severe systemic infections:** Septicaemia, bacteraemia, peritonitis, infections in immuno-suppressed patients.

Gonorrhoea: Urethral, rectal and pharyngeal gonorrhoea caused by B-lactamase producing organisms or organisms moderately sensitive to penicillin.

CONTRAINDICATIONS:

Ciprofloxacin is contra-indicated in patients who have shown hypersensitivity to ciprofloxacin or other quinolone anti-infectives. Except in cases of exacerbations of cystic fibrosis associated with *P. aeruginosa* (in patients aged 5-17 years) and inhalation anthrax, ciprofloxacin is contra-indicated in children and growing adolescents unless the benefits of treatment are considered to outweigh the risks.

DRUG INTERACTIONS: Antacids (containing Magnesium, Calcium, and Aluminium will prevent absorption), theophylline, clozapine, tacrine, ropinirol, tizanidine.

UNWANTED SIDE EFFECTS: CNS: restlessness, seizures GI: vomiting, dyspepsia, flatulence, abdominal pain, GU: crystalluria, SJS: itching

PREGNANCY AND LACTATION: Pregnancy Category C: Ciprofloxacin is not recommended during pregnancy & lactation.

DOSEAGE & ADMINISTRATION: Dosage administration of ciprofloxacin depends upon the severity of infections. For mild to moderate case 250mg to 500mg are recommended

and for severe infections 750mg is recommended.

ADULT DOSAGE GUIDELINES

INDICATIONS	SEVERITY	DOSE (b.i.d)	DURATIONS
UTIs	Mild/Moderate	250mg	7 to 14 Days
	Severe/Complicated	500mg	7 to 14 Days
Lower RTIs	Mild/Moderate	500mg	7 to 14 Days
	Severe/Complicated	750mg	7 to 14 Days
SSTIs	Mild/Moderate	500mg	40 Days
Bone & Joint	Mild/Moderate	500mg	7 to 14 Days
Infections	Severe/Complicated	750mg	7 to 14 Days
Typhoid Fever	Mild/Moderate	500 mg	10 Days
Urethral Gonococcal Infections	Uncomplicated	250mg	Single dose

CHILDREN AND ADOLESCENTS

INDICATIONS	DOSE	DURATIONS
Cystic fibrosis	20mg/kg per dose b.i.d (max. of 750mg)	10-14 days
Complicated UTIs & pyelonephritis	10-20mg/kg per dose b.i.d (max. of 750mg)	10-21 days
Typhoid	15mg/kg per dose b.i.d	5-7 days
Shigellosis	15mg/kg per dose b.i.d	3 days
Other severe infections	20mg/kg per dose b.i.d (max. of 750mg)	As per type of infections

DOSEAGE IN PATIENTS WITH IMPAIRED RENAL FUNCTION

CREATININE CLEARANCE (mL/min)	DOSE
> 50	See Usual Dosage
30 - 50	250 - 500 mg q 12 h
5 - 29	250 - 500 mg q 18 h
Patients on hemodialysis or Peritoneal dialysis	250 - 500 mg q 24 h (after dialysis)

IV INFUSION DOSAGE

Indications	Severity	Dose	Duration
Urinary Tract	Mild/Moderate	200 mg (bd)	7-14 Days
	Severe/Complicated	400mg (bd)	7-14 Days
Lower Respiratory Tract	Mild/Moderate	400 mg (bd)	7-14 Days
	Severe/Complicated	400mg (bd)	7-14 Days
Nosocomial Pneumonia	Mild/Moderate/Severe	400mg (qd)	10-14 Days
	Mild/Moderate	400 mg (bd)	7-14 Days
Skin and Skin Structure	Mild/Moderate	400 mg (bd)	7-14 Days
	Severe/Complicated	400 mg (bd)	7-14 Days
Bone and Joint	Mild/Moderate	400 mg (bd)	> 4 Weeks
	Severe/Complicated	400mg (qd)	> 4 Weeks
Intra-Abdominal	Mild/Moderate	400 mg (bd)	7-14 Days
	Complicated	400 mg (bd)	7-14 Days
Acute Sinusitis	Mild/Moderate	400 mg (bd)	10 Days
	Chronic Bacterial Prostatitis	Mild/Moderate	400 mg (bd)

DIPRO I.V. should be administered to adults by intravenous infusion over a period of 60 minutes at dosages described in the Dosage Guidelines table. Slow infusion of a dilute solution into a larger vein will minimize patient discomfort and reduce the risk of venous irritation. Oral suspension can be taken independent of mealtimes. If taken on an empty stomach, the active substance is absorbed more rapidly. Ciprofloxacin should not be taken with dairy products (e.g. milk, yoghurt) or mineral-fortified fruit juice (e.g. calcium-fortified orange juice).

DIRECTION FOR RECONSTITUTION: To make 60ml suspension add some cool boiled water. Invert bottle and shake well until all granules are dispersed. Then slowly add more water up to the mark on the label. Reconstituted suspension should be stored in cool place, avoid exposure to heat & freezing. Use within 14-days. Shake Well Before Use.

INSTRUCTIONS:

DIPRO Tablet; DIPRO Oral Suspension: Store below

30°C. Protect from heat, light and moisture. **DIPRO Infusion:** Store below 30°C. Protect from heat and light. Keep all medicines out of the reach of children. Do not Refrigerate.

To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

DIPRO (Ciprofloxacin) 250mg Tablets U.S.P. are available in Alu-Alu blister pack of 1x10's with leaf insert. **DIPRO (Ciprofloxacin) 500mg Tablets U.S.P.** are available in Alu-Alu blister pack of 1x10's with leaf insert. **DIPRO (Ciprofloxacin) 125mg/5ml For Oral Suspension** is available in 60ml glass bottle with leaf insert.

DIPRO (Ciprofloxacin) 250mg/5ml For Oral Suspension is available in 60ml glass bottle with leaf insert.

DIPRO (Ciprofloxacin) 200mg/100ml I.V. Infusion B.P. is available in 100ml glass vial with hanger & leaf insert.

Manufactured for:

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