

# Efecip

(Ciprofloxacin)

250mg & 500mg  
Tablets U.S.P.

For Oral Suspension U.S.P.  
125mg/5mL & 250mg/5mL

I.V. Infusion B.P.  
200mg / 100mL

۱۲۵ ملی گرام / ۵ ملی لیٹر  
۲۵۰ ملی گرام / ۵ ملی لیٹر  
اورل سسپنشن یو۔ ایس۔ پی۔

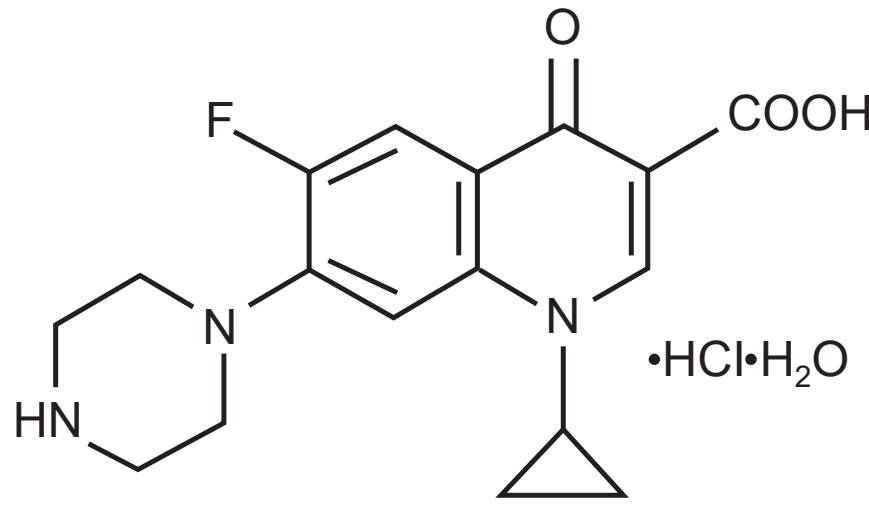
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۲۰۰ ملی گرام / ۱۰۰ ملی لیٹر  
آئی۔ وی۔ انفیوژن پی۔ پی۔

صرف وریدی استعمال کیلئے

ایفی سیپ  
(سیپروفلوکساسین)

## DESCRIPTION:

Efecip 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:** SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS:

See full prescribing information for complete boxed warning.

• Fluoroquinolones, including Ciprofloxacin, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred

together, including:

- Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

Discontinue Ciprofloxacin immediately and avoid the use of fluoroquinolones, including Ciprofloxacin, in patients who experience any of these serious adverse reactions

• Fluoroquinolones, including Ciprofloxacin, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Ciprofloxacin in patients with known history of myasthenia gravis.

• Because fluoroquinolones, including Ciprofloxacin, have been associated with serious adverse reactions (5.1-5.15), reserve CIPRO for use in patients who have no alternative treatment options for the following indications:

- Acute exacerbation of chronic bronchitis
- Acute uncomplicated cystitis
- Acute sinusitis

## COMPOSITION:

**Efecip® 250mg Tablets U.S.P.:** Each film-coated tablet Contains: Ciprofloxacin HCl U.S.P. eq. to Ciprofloxacin...250mg

**Efecip® 500mg Tablets U.S.P.:** Each film-coated tablet Contains: Ciprofloxacin HCl U.S.P. eq. to Ciprofloxacin...500mg

**Efecip® For Oral Suspension U.S.P. 125mg/5ml:** Each 5mL of reconstituted suspension contains: Ciprofloxacin ( as HCl ) taste masked micro pellets equivalent to Ciprofloxacin ..... 125mg

**Efecip® For Oral Suspension U.S.P. 250mg/5ml:** Each 5mL of reconstituted suspension contains: Ciprofloxacin ( as HCl ) taste masked micro pellets equivalent to Ciprofloxacin ..... 250mg

**Efecip® 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** Co-

rynebacterium diphtheriae

Corynebacterium spp.

Staphylococcus aureus

Streptococcus agalactiae

Bacillus anthracis

**Gram-positive aerobes**

Enterococci

Enterococcus faecalis

Staphylococcus epidermis

Staphylococcus haemolyticus

Streptococcus anginosus

Streptococcus milleri

Streptococcus mitis

Streptococcus pneumoniae

Streptococcus pyogenes

**Gram-negative bacteria**

Gram-negative bacteria

Escherichia coli

Haemophilus influenzae

Haemophilus parainfluenzae

Klebsiella spp.

Legionella spp.

Moraxella catarrhalis

Neisseria gonorrhoeae

Neisseria meningitidis

Proteus mirabilis

Pseudomonas aeruginosa

Salmonella spp.

Salmonella typhi

Shigella spp.

Vibrio spp.

**Gram-negative aerobes**

Alcaligenes spp.

Listeria monocytogenes

Listeria spp.

**Anaerobes**

Bacteroides ureolyticus

Clostridium perfringens

Peptococcus spp.

Veillonella parvula

**Other Pathogens**

Chlamydia spp.

Mycobacterium fortuitum

Mycobacterium tuberculosis

Mycoplasma hominis

**PHARMACODYNAMICS:**

Ciprofloxacin is a synthetic 4-quinolone derivative, with bactericidal activity. It acts via inhibition of bacterial DNA gyrase, ultimately resulting in 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, empyema, Gram-negative

paneuemonia. **Ear, nose and throat infections:** Mastoiditis, otitis media and sinusitis, especially if due to Gram-negative bacteria (including *Pseudomonas* spp.). Ciprofloxacin is not recommended for the treatment of acute tonsillitis. **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. **Infections of the Bone and Joints:** Osteomyelitis, septic arthritis. **Intra-abdominal infections:** Peritonitis, intra-abdominal abscesses. **Infections of the biliary tract:** Cholangitis, cholecystitis, empyema 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, Skin: itching

### PREGNANCY AND LACTATION:

Ciprofloxacin is not recommended during pregnancy & lactation.

### DOSAGE & 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
<i>UTIs</i>	Mild/Moderate	250mg	7 to 14 Days
	Severe/Complicated	500mg	7 to 14 Days
<i>Lower RTIs</i>	Mild/Moderate	500mg	7 to 14 Days
	Severe/Complicated	750mg	7 to 14 Days
<i>SSTIs</i>	Mild/Moderate	500mg	40 Days
<i>Bone &amp; Joint</i>	Mild/Moderate	500mg	7 to 14 Days
<i>Infections</i>	Severe/Complicated	750mg	7 to 14 Days
<i>Typhoid Fever</i>	Mild/Moderate	500 mg	10 Days
<i>Urethral Gonococcal Infections</i>	Uncomplicated	250mg	Single dose

## CHILDREN AND ADOLESCENTS

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

## DOSAGE 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 (bid)	7-14 Days
	Severe/Complicated	400mg (bid)	7-14 Days
Lower Respiratory Tract	Mild/Moderate	400 mg (bid)	7-14 Days
	Severe/Complicated	400mg (qid)	7-14 Days
Nosocomial Pneumonia	Mild/Moderate/Severe	400mg (qid)	10-14 Days
Skin and Skin Structure	Mild/Moderate	400 mg (bid)	7-14 Days
	Severe/Complicated	400 mg (bid)	7-14 Days
Bone and Joint	Mild/Moderate	400 mg (bid)	> 4-6 Weeks
	Severe/Complicated	400mg (qid)	> 4-6 Weeks
Intra-Abdominal	Complicated	400 mg (bid)	7-14 Days
Acute Sinusitis	Mild/Moderate	400 mg (bid)	10 Days
Chronic Bacterial Prostatitis	Mild/Moderate	400 mg (bid)	28 Days

Efecip 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 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 store in cool place, avoid exposure to heat & freezing. Use within 14-days. Shake Well Before Use.

### **INSTRUCTIONS:**

Dosage as directed by the physician.

**For Tablets and Oral Suspension:** Store below 30°C. Protect from heat, light and moisture.

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

## PRESENTATION:

- Efecip® (Ciprofloxacin) 250mg tablets, U.S.P. are available in Alu-Alu blister pack of 1x10's.
- Efecip® (Ciprofloxacin) 500mg tablets, U.S.P. are available in Alu-Alu blister pack of 1x10's.
- Efecip® (Ciprofloxacin) 125mg/5ml For Oral Suspension available in 60ml glass bottle.
- Efecip® (Ciprofloxacin) 250mg/5ml For Oral Suspension available in 60ml glass bottle.
- Efecip® (Ciprofloxacin) 200mg I.V. Infusion, B.P. available in 100ml glass vial with HDPE hanger.

## سپنشن تیار کرنے کیلئے

اُبلایا ہوا ٹھنڈا پانی بوتل میں شامل کریں اور بوتل کو اچھی طرح ہلایں تاکہ تمام دوا اچھی طرح حل ہو جائے۔  
پھر مزید پانی لیبل پر دیئے ہوئے نشان تک شامل کر دیں اور بوتل کو دوبارہ اچھی طرح ہلایں۔  
استعمال سے پہلے بوتل کو اچھی طرح ہلایں۔

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔  
ٹیبلیٹس؛ اورل سپنشن: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔  
گرمی، روشنی اور نمی سے محفوظ رکھیں۔  
انفیوژن: ۳۰ ڈگری سینٹی گریڈ سے کم پر رکھیں۔  
گرمی اور روشنی سے محفوظ رکھیں۔ منجمد ہونے سے بچائیں۔  
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

For detailed information:

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