Ciprofloxacin Tablets (ciprofloxacin) - Drug Summary

Dr. Reddy's Laboratories Inc

Related Drug Information

Ciprofloxacin Oral
(ciprofloxacin, ciprofloxacin hydrochloride)

BOXED WARNING

Fluoroquinolones are associated w/ an increased risk of tendinitis and tendon rupture in all ages. Risk is further increased in patients >60 yrs of age, patients taking corticosteroids, and patients w/ kidney, heart, or lung transplants. May exacerbate muscle weakness w/ myasthenia gravis; avoid in patients w/ known history of myasthenia gravis.

COMMON BRAND NAMES

Cipro, Ciprofloxacin Oral

THERAPEUTIC CLASS

Fluoroquinolone

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Urinary Tract Infections

250-500mg q12h for 7-14 days

Uncomplicated Cystitis

Acute:
250mg q12h for 3 days

Chronic Bacterial Prostatitis

500mg q12h for 28 days

Lower Respiratory Tract Infections

500-750mg q12h for 7-14 days

Acute Bacterial Sinusitis

500mg q12h for 10 days

Skin and Skin Structure Infections

500-750mg q12h for 7-14 days

Bone/Joint Infections

500-750mg q12h for 4-8 weeks

Intra-Abdominal Infections

Complicated:
500mg q12h for 7-14 days, in conjunction w/ metronidazole

Diarrhea

Infectious:
500mg q12h for 5-7 days

Typhoid Fever

500mg q12h for 10 days

Gonococcal Infections

Uncomplicated Urethral and Cervical:
250mg single dose

Inhalational Anthrax (Postexposure)

500mg q12h for 60 days

Begin as soon as possible after suspected or confirmed exposure

Plague

500-750mg q12h for 14 days

Begin as soon as possible after suspected or confirmed exposure

Conversions

Switching from IV to Oral:
200mg IV q12h: 250mg tab q12h
400mg IV q12h: 500mg tab q12h
400mg IV q8h: 750mg tab q12h

PEDIATRIC DOSAGE & INDICATIONS

Urinary Tract Infections

Complicated UTIs or Pyelonephritis:
1-17 Years:
10-20mg/kg q12h for 10-21 days
Max: 750mg/dose; not to be exceeded even if >51kg

Inhalational Anthrax (Postexposure)

15mg/kg q12h for 60 days
Max: 500mg/dose

Begin as soon as possible after suspected or confirmed exposure

Plague

15mg/kg q8-12h for 10-21 days
Max: 500mg/dose

Begin as soon as possible after suspected or confirmed exposure

DOSING CONSIDERATIONS

Renal Impairment
Adults:
CrCl 30-50mL/min: 250-500mg q12h
CrCl 5-29mL/min: 250-500mg q18h
Hemodialysis/Peritoneal Dialysis: 250-500mg q24h (after dialysis)
Severe Impairment w/ Severe Infection: Unit dose of 750mg may be administered at intervals noted above

ADMINISTRATION

Oral route

Take w/ or w/o food.
Administer ≥2 hrs before or 6 hrs after Mg^{2+}/aluminum antacids; polymeric phosphate binders or sucralfate; Videx (didanosine) chewable/buffered tabs or pediatric powder for oral sol; other highly buffered drugs; or other products containing Ca^{2+}, iron, or zinc.
Avoid concomitant administration w/ dairy products or Ca^{2+}-fortified juices alone; may take w/ a meal that contains these products.
Assure adequate hydration.

Reconstitution
Pour the microcapsules completely into the larger bottle of diluent; do not add water to the sus.
Close the larger bottle completely and shake vigorously for about 15 sec.
May store reconstituted product below 30°C (86°F) for 14 days; protect from freezing.

HOW SUPPLIED

Sus: (Cipro) 250mg/5mL, 500mg/5mL [100mL]; **Tab:** 100mg, 750mg; (Cipro) 250mg, 500mg

CONTRAINDICATIONS

Concomitant administration w/ tizanidine.

WARNINGS/PRECAUTIONS

Not a drug of 1st choice in the treatment of presumed or confirmed pneumonia secondary to *Streptococcus pneumoniae*. Not a drug of 1st choice in the pediatric population due to an increased incidence of adverse events. Caution w/ history of tendon disorders; d/c if patient experiences pain, swelling, inflammation, or rupture of tendon. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions reported; d/c immediately at the 1st appearance of a skin rash, jaundice, or any sign of hypersensitivity, and institute supportive measures. Severe hepatotoxicity, including hepatic necrosis, life-threatening hepatic failure, and fatal events, reported; d/c immediately if signs and symptoms of hepatitis occur. Convulsions, status epilepticus, increased intracranial

pressure (including pseudotumor cerebri), toxic psychosis, and other CNS events reported; d/c and institute appropriate measures if CNS events occur. Caution w/ epilepsy and CNS disorders (eg, severe cerebral arteriosclerosis, history of convulsion, reduced cerebral blood flow), or other risk factors that may predispose to seizures or lower the seizure threshold; d/c if seizures occur. *Clostridium difficile*-associated diarrhea (CDAD) reported; may need to d/c if CDAD is suspected or confirmed. Cases of sensory or sensorimotor axonal polyneuropathy resulting in paresthesias, hypoesthesias, dysesthesias, and weakness reported; d/c immediately if symptoms of peripheral neuropathy occur. May prolong the QT interval; avoid w/ known QT interval prolongation and risk factors for QT prolongation/torsades de pointes (eg, congenital long QT syndrome, uncorrected electrolyte imbalance, cardiac disease). Increased incidence of adverse reactions related to joints and/or surrounding tissues observed in pediatric patients. Crystalluria reported; maintain hydration and avoid alkalinity of urine. May cause photosensitivity/phototoxicity reactions; d/c if phototoxicity occurs. Avoid excessive exposure to sun/UV light. May result in bacterial resistance if used in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication. Has not been shown to be effective in the treatment of syphilis; antimicrobial agents used in high dose for short periods to treat gonorrhea may mask or delay symptoms of incubating syphilis. Caution in elderly.

ADVERSE REACTIONS

N/V, diarrhea, abnormal LFTs, rash.

DRUG INTERACTIONS

See Boxed Warning and Contraindications. Avoid concomitant administration w/ dairy products (eg, milk, yogurt), or Ca^{2+}-fortified juices alone; absorption may be reduced. May increase levels of CYP1A2 substrates (eg, theophylline, methylxanthines, olanzapine), duloxetine, or sildenafil. Use w/ caution and monitor for sildenafil toxicity. Avoid use w/ duloxetine; if unavoidable, monitor for duloxetine toxicity. Increased theophylline levels may increase the risk of developing CNS or other adverse reactions; if coadministration cannot be avoided, monitor theophylline levels and adjust dose. May inhibit the formation of paraxanthine after caffeine administration (or pentoxifylline containing products); monitor for xanthine toxicity and adjust dose as necessary. Monitor for clozapine- or ropinirole-related adverse reactions and adjust dose of clozapine or ropinirole during and shortly after coadministration. Avoid w/ Class IA (eg, quinidine, procainamide) and Class III (eg, amiodarone, sotalol) antiarrhythmics, TCAs, macrolides, antipsychotics, and any other drug known to prolong the QT interval; may further prolong the QT interval. Hypoglycemia reported w/ oral antidiabetic agents, mainly sulfonylureas (eg, glyburide, glimepiride); monitor blood glucose. May alter serum levels of phenytoin; monitor phenytoin therapy, including phenytoin levels during and shortly after coadministration. Transient SrCr elevations w/ cyclosporine; monitor renal function. May increase effects of oral anticoagulants; monitor PT and INR frequently during and shortly after coadministration. May increase levels and toxic reactions of methotrexate; carefully monitor w/ concomitant use. High-dose quinolones in combination w/ NSAIDs (not acetyl salicylic acid) may provoke convulsions. Antacids, sucralfate, multivitamins, and other multivalent cation-containing products (eg, Mg^{2+}/aluminum antacids, polymeric phosphate binders, Videx [didanosine] chewable/buffered tab or pediatric powder, products containing Ca^{2+}, iron, or zinc; dairy product) may decrease absorption, resulting in lower serum and urine levels than desired; administer ≥2 hrs before or 6 hrs after multivalent cation-containing products administration. Probenecid may increase levels; use w/ caution. Caution w/ drugs that may lower seizure threshold.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Found in breast milk; not for use in nursing.

MECHANISM OF ACTION

Fluoroquinolone; inhibits the enzymes topoisomerase II (DNA gyrase) and topoisomerase IV (both Type II topoisomerases), which are required for bacterial DNA replication, transcription, repair, and recombination.

PHARMACOKINETICS

Absorption: T_{max}=1-2 hrs. (Tab) Absolute bioavailability (approx 70%). Administration of various doses resulted in different pharmacokinetic parameters. **Distribution:** Plasma protein binding (20-40%); found in breast milk. **Elimination:** Urine (approx 40-50%, unchanged), feces (approx 20-35%), bile; $T_{1/2}$=4 hrs.

ASSESSMENT

Assess for risk factors for developing tendinitis and tendon rupture, history of myasthenia gravis, drug hypersensitivity, epilepsy, CNS disorders or other risk factors that may predispose to seizures or lower seizure threshold, QT interval prolongation, renal dysfunction, previous liver damage, pregnancy/nursing status, and possible drug interactions. Obtain baseline culture and susceptibility tests. Perform serologic test for syphilis in patients w/ gonorrhea.

MONITORING

Monitor for tendinitis or tendon rupture, exacerbation of myasthenia gravis, signs/symptoms of hypersensitivity reactions, QT prolongations, CNS effects, CDAD, hepatotoxicity, peripheral neuropathy, musculoskeletal disorders (pediatric patients), crystalluria, photosensitivity/phototoxicity reactions, and other adverse reactions. Monitor PT and INR if coadministered w/ an oral anticoagulant (eg, warfarin). Monitor renal function. Perform periodic culture and susceptibility testing. Perform follow-up serologic test for syphilis after 3 months in patients w/ gonorrhea.

PATIENT COUNSELING

Inform that drug treats only bacterial, not viral, infections. Instruct to take exactly ud; inform that skipping doses or not completing full course of therapy may decrease effectiveness and increase bacterial resistance. Advise to drink fluids liberally. Instruct to avoid concomitant use w/ dairy products or Ca^{2+}-fortified juices alone, but explain that drug may be taken w/ a meal that contains these products. Advise to notify physician if tendon disorder symptoms occur; instruct to d/c therapy and rest/refrain from exercise. Instruct to notify physician if myasthenia gravis, liver injury, or photosensitivity/phototoxicity symptoms occur. Instruct to notify physician of any history of convulsions. Advise to assess reaction to therapy before engaging in activities that require mental alertness or coordination; instruct to notify physician if persistent headache w/ or w/o blurred vision occurs. Advise to contact physician as soon as possible if watery and bloody stools (w/ or w/o stomach cramps and fever) develop even

as late as ≥2 months after last dose. Instruct to d/c and notify physician if hypersensitivity reactions or symptoms of peripheral neuropathy develop. Instruct to inform physician of any personal or family history of QT prolongation or proarrhythmic conditions and if symptoms of prolongation of the QT interval occur. Counsel caregiver to inform physician if child has joint-related problems prior to, during, or after therapy. Advise to seek medical help immediately if experiencing seizures, palpitations, or breathing difficulty. Instruct to minimize or avoid exposure to natural/artificial sunlight (tanning beds or UVA/B treatment). Instruct to contact physician if low blood sugar occurs. Inform that efficacy studies of ciprofloxacin could not be conducted in humans w/ plague and anthrax for feasibility reasons and that approval for these conditions was therefore based on efficacy studies conducted in animals.

STORAGE

Tab: 20-25°C (68-77°F). (Cipro) Excursions permitted to 15-30°C (59-86°F). **Microcapsules and Diluent:** <25°C (77°F); excursions permitted from 15-30°C (59-86°F). **Reconstituted Sus:** 25°C (77°F); excursions permitted from 15-30°C (59-86°F). Store reconstituted product for 14 days. Protect from freezing.

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