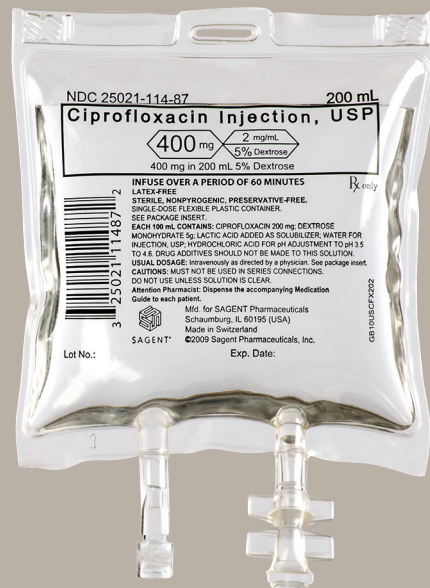




## CIPROFLOXACIN Injection, USP

Consider these SAGENT benefits:

- Available in:
  - 200 mg per 100 mL in 5% dextrose premix bags
  - 400 mg per 200 mL in 5% dextrose premix bags
- Ready-to-use premix bags facilitate adherence to USP <797>
- LATEX-FREE
- Preservative-free
- Functional medication port
- Discover **PreventIV Measures™** packaging features:
  - Easy-to-read drug name and dosage strength
  - Bar coding on the overwrap and the bag
  - Distinctive design on the overwrap to aid in differentiating premix bag products



Please see full prescribing information for CIPROFLOXACIN Injection, USP, enclosed.



### Discover Injectables Excellence™

# CIPROFLOXACIN Injection, USP



Innovator Product Name: CIPRO® I.V. (*Cipro I.V. is a registered trademark of BAYER AKTIENGESELLSCHAFT JOINT STOCK COMPANY.*)

NDC Number	Description	Strength	Fill Volume	Concentration	Unit of Sale	Bar Coded
25021-114-82	Premix Bag	200 mg	100 mL	2 mg per mL	24 Bags	✓
25021-114-87	Premix Bag	400 mg	200 mL	2 mg per mL	24 Bags	✓

This SAGENT product meets stringent FDA requirements and is AP rated, LATEX-FREE and preservative-free.

To order, or for more information about discovering Injectables Excellence™ with SAGENT, contact your sales representative, call 1-866-625-1618 or visit [www.SagentPharma.com](http://www.SagentPharma.com).

Listening. Responding. Delivering. That's Injectables Excellence.™ That's SAGENT Pharmaceuticals.

## CIPROFLOXACIN Injection, USP

### INDICATIONS

CIPROFLOXACIN Injection, USP is indicated for the treatment of the following infections caused by susceptible strains of designated microorganisms in specific conditions and patient populations when the intravenous administration offers a route of administration advantage to the patient: urinary tract infections, lower respiratory tract infections, acute exacerbation of chronic bronchitis, nosocomial pneumonia, skin and skin structure infections, bone and joint infections, complicated intra-abdominal infections, acute sinusitis and chronic bacterial prostatitis and in the treatment of inhalational anthrax (post-exposure).

### IMPORTANT SAFETY INFORMATION

#### WARNING:

Fluoroquinolones, including CIPROFLOXACIN Injection, USP, 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 (see WARNINGS).

Fluoroquinolones, including CIPROFLOXACIN Injection, USP, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid CIPROFLOXACIN Injection, USP in patients with known history of myasthenia gravis (see WARNINGS).

#### CONTRAINDICATIONS

- CIPROFLOXACIN Injection, USP is contraindicated in persons with a history of hypersensitivity to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.
- Concomitant administration with tizanidine is contraindicated.

#### WARNINGS AND PRECAUTIONS

- Fluoroquinolones, including CIPROFLOXACIN Injection, USP, are associated with an increased risk of tendinitis and tendon rupture in all ages. CIPROFLOXACIN Injection, USP should be discontinued if the patient experiences pain, swelling, inflammation or rupture of a tendon. Patients should be advised to rest at the first sign of tendinitis or tendon rupture, and to contact their healthcare provider regarding changing to a non-quinolone antimicrobial drug.
- Fluoroquinolones, including CIPROFLOXACIN Injection, USP, have neuromuscular blocking activity and may exacerbate muscle weakness in persons with myasthenia gravis. Avoid ciprofloxacin in patients with known history of myasthenia gravis.
- The safety and effectiveness of ciprofloxacin in pregnant and lactating women have not been established.
- Ciprofloxacin should be used in pediatric patients only for infections listed in the INDICATIONS AND USAGE section of the full prescribing information.
- Ciprofloxacin is an inhibitor of the hepatic CYP1A2 enzyme pathway. Coadministration of ciprofloxacin and other drugs primarily metabolized by CYP1A2 results in increased plasma concentrations of the coadministered drug.
- Convulsions, increased intracranial pressure and toxic psychosis have been reported in patients receiving quinolones, including ciprofloxacin.
- Serious and fatal reactions have been reported in patients receiving concurrent administration of intravenous ciprofloxacin and theophylline.

- Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving quinolone therapy.
- Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all anti-bacterial agents, including ciprofloxacin, and may range in severity from mild diarrhea to fatal colitis.
- Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including ciprofloxacin.
- Intravenous ciprofloxacin should be administered by slow infusion over a period of 60 minutes. Local I.V. site reactions have been reported with the intravenous administration of ciprofloxacin. These reactions are more frequent if infusion time is 30 minutes or less or if small veins of the hand are used.

#### ADVERSE REACTIONS

The most frequently reported drug related events, from clinical trials of all formulations, all dosages, all drug-therapy durations, and for all indications of ciprofloxacin therapy were nausea, diarrhea, abnormal liver function test, vomiting, central nervous system disturbances, headache, eosinophilia, restlessness, local I.V. site reaction, and rash.

#### OVERDOSAGE

In the event of acute overdosage, the patient should be carefully observed and given supportive treatment, including monitoring of renal function. Adequate hydration must be maintained.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please see full prescribing information for CIPROFLOXACIN Injection, USP.



SAGENT™

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