The convenience of premix bags

Safety is CumulatIV™
- Available in three premix bags (250 mg per 50 mL, 500 mg per 100 mL and 750 mg per 150 mL) in 5% dextrose
- Premix bags are DEHP-free and PVC-free
- Ready-to-use premix bags facilitate adherence to USP <797>
- Preservative-free, AP rated, bar coded and not made with natural rubber latex

Packaging is InformatIV™
- Easy-to-read drug name and strengths printed on bags and front and back of overwraps
- Distinctive colors on bags to distinguish one strength from another
- Unique label design helps in accurate product selection

Please see full prescribing information, including boxed warning, for LEVOFLOXACIN Injection in 5% Dextrose, enclosed.

Every SAGENT® Product Features...
LEVOFLOXACIN Injection in 5% Dextrose

Innovator Product Name: LEVAQUIN®

(Levaquin is a registered trademark of Daiichi Sankyo Company, Limited Corporation.)

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Description</th>
<th>Strength</th>
<th>Fill Volume</th>
<th>Concentration</th>
<th>Closure</th>
<th>Unit of Sale</th>
<th>Bar Coded</th>
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<tbody>
<tr>
<td>25021-132-81</td>
<td>Premix Bag*</td>
<td>250 mg</td>
<td>50 mL</td>
<td>5 mg per mL</td>
<td>N/A</td>
<td>24 Bags</td>
<td></td>
</tr>
<tr>
<td>25021-132-82</td>
<td>Premix Bag*</td>
<td>500 mg</td>
<td>100 mL</td>
<td>5 mg per mL</td>
<td>N/A</td>
<td>24 Bags</td>
<td></td>
</tr>
<tr>
<td>25021-132-83</td>
<td>Premix Bag*</td>
<td>750 mg</td>
<td>150 mL</td>
<td>5 mg per mL</td>
<td>N/A</td>
<td>24 Bags</td>
<td></td>
</tr>
</tbody>
</table>

*PVC-free, DEHP-free

This SAGENT product meets stringent FDA requirements and is AP rated, preservative-free and not made with natural rubber latex.

To order, or for more information about how to Discover Injectables Excellence® with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

### CONTRAINDICATIONS

Known hypersensitivity to levofloxacin or other quinolones.

### WARNINGS AND PRECAUTIONS

- Fluoroquinolones, including levofloxacin, have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These reactions can occur within hours to weeks after starting levofloxacin. Patients of any age or without pre-existing risk factors have experienced these adverse reactions. Discontinue levofloxacin immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including levofloxacin, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.

- Tendinitis and Tendon Rupture: Fluoroquinolones, including levofloxacin, have been associated with an increased risk of tendinitis and tendon rupture in all ages. Tendinitis or tendon rupture can occur within hours or days of starting levofloxacin or as long as several months after completion of fluoroquinolone therapy. The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is increased in patients over 60 years of age, in those taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Discontinue levofloxacin immediately 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. Avoid levofloxacin in patients who have a history of tendon disorders or tendon rupture.

- Peripheral Neuropathy: Fluoroquinolones, including levofloxacin, have been associated with an increased risk of peripheral neuropathy. Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dyesthesias and weakness have been reported in patients receiving fluoroquinolones, including levofloxacin. Symptoms may occur soon after initiation of levofloxacin and may be irreversible in some patients. Discontinue levofloxacin immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation. Avoid fluoroquinolones, including levofloxacin, in patients who have previously experienced peripheral neuropathy.

- Central Nervous System Effects: Fluoroquinolones, including levofloxacin, have been associated with an increased risk of central nervous system (CNS) effects, including convulsions, toxic psychoses, increased intracranial pressure (including pseudotumor cerebri). Fluoroquinolones may also cause central nervous system stimulation which may lead to tremors, restlessness, anxiety, lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, and insomnia. Suicidal thoughts, and attempted or completed suicide may also occur, especially in patients with a medical history of depression, or an underlying risk factor for depression.

(continued on next page)
LEVOFLOXACIN Injection in 5% Dextrose

IMPORTANT SAFETY INFORMATION

(continued from previous page)

These reactions may occur following the first dose. If these reactions occur in patients receiving levofloxacin, discontinue levofloxacin and institute appropriate measures.

- **Exacerbation of Myasthenia Gravis:** Fluoroquinolones, including levofloxacin, have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. Avoid levofloxacin in patients with a known history of myasthenia gravis.

- **Other Serious and Sometimes Fatal Adverse Reactions:** Other serious and sometimes fatal adverse reactions have been reported rarely in patients receiving therapy with fluoroquinolones, including levofloxacin. These events may be severe and generally occur following the administration of multiple doses. Discontinue levofloxacin immediately at the first appearance of skin rash, jaundice, or any other sign of hypersensitivity and institute supportive measures.

- **Hypersensitivity Reactions:** Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with fluoroquinolones, including levofloxacin.

- **Hepatotoxicity:** Post-marketing reports of severe hepatotoxicity (including acute hepatitis and fatal events) have been received for patients treated with levofloxacin. Levofloxacin should be discontinued immediately if the patient develops signs and symptoms of hepatitis.

- **Clostridium difficile-Associated Diarrhea:** *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including levofloxacin, and may range in severity from mild diarrhea to fatal colitis.

- **Prolongation of the QT Interval:** Some fluoroquinolones, including levofloxacin, have been associated with prolongation of the QT interval on the electrocardiogram and infrequent cases of arrhythmia. Fluoroquinolones, including levofloxacin, are contraindicated in patients with known QT prolongation or congenital long QT syndrome. Prolongation of the QT interval may also occur with other drugs that can prolong the QT interval, such as certain antihistamines, antipsychotics, antiarrhythmics, and some antibiotics. Avoid levofloxacin in patients with a known history of cardiac conduction abnormalities.

- **Other Serious and Sometimes Fatal Adverse Reactions:** These include: prolongation of the QT interval, arrhythmias, lidocaine toxicity, and rhabdomyolysis.

- **Photosensitivity/Phototoxicity:** Moderate to severe photosensitivity/phototoxicity reactions, the latter of which may manifest as exaggerated sunburn reactions (e.g., burning, erythema, exudation, vesicles, blistering, edema) involving areas exposed to light (typically the face, "V" area of the neck, extensor surfaces of the forearms, dorsa of the hands), can be associated with the use of fluoroquinolones after sun or UV light exposure.

- **Development of Drug Resistant Bacteria:** Prescribing levofloxacin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

- **Pregnancy Category C:** Based on data on other fluoroquinolones and very limited data on levofloxacin, it can be presumed that levofloxacin will be excreted in human milk. Avoid levofloxacin in nursing mothers.

- **Renal Impairment:** Clearance of levofloxacin is substantially reduced and plasma elimination half-life is substantially prolonged in patients with impaired renal function (creatinine clearance < 50 mL/min), requiring dosage adjustment in such patients to avoid accumulation. Neither hemodialysis nor continuous ambulatory peritoneal dialysis (CAPD) is effective in removal of levofloxacin from the body, indicating that supplemental doses of levofloxacin are not required following hemodialysis or CAPD.

**ADVERSE REACTIONS**

The most common adverse reactions (≥ 3%) were nausea, headache, diarrhea, insomnia, constipation and dizziness.

**OVERDOSAGE**

In the event of an acute overdosage, the stomach should be emptied. The patient should be observed and appropriate hydration maintained. Levofloxacin is not efficiently removed by hemodialysis or peritoneal dialysis.

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

Please see full prescribing information for LEVOFLOXACIN Injection in 5% Dextrose.
Dosage in patients with normal renal function (2.1)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of

Pneumoniae [see Dosage and Administration (2.1)]

1.3 Community-Acquired Pneumonia: 5-day Treatment Regimen

The usual dose of Levofloxacin Injection is 250 mg or 500 mg administered by slow infusion

2 DOSAGE AND ADMINISTRATION

- Moderate to severe photosensitivity/phototoxicity reactions, the latter of which may

- Acute bacterial sinusitis

- Staphylococcus aureus

- Tendinitis and tendon rupture (5.2)

- Tissue Disorders

- Acute bacterial exacerbation of chronic bronchitis (1.13) 500 mg 7

- Acute bacterial sinusitis: 5-day and 10 to 14 day Treatment Regimens

- Exacerbation of myasthenia gravis

- Metabolic and Endocrine

- Antidiabetic agents

- Levofloxacin Injection should not be co-administered with any solution containing multivalent

- Levofloxacin Injection

- Administer levofloxacin with caution in the presence of renal insufficiency. Careful clinical

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When available, the clinical microbiology laboratory should provide the results of warfarin, theophylline, cyclosporine, digoxin, probenecid, and cimetidine has been evaluated.

Levofloxacin has been shown to be active against most isolates of the following bacteria both in vitro and in vivo.

Table 10: Quality Control Ranges for Susceptibility Testing

<table>
<thead>
<tr>
<th>Organism</th>
<th>NDC</th>
<th>API</th>
<th>NTID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli</td>
<td>5</td>
<td>0.02</td>
<td>0.002</td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>16</td>
<td>2</td>
<td>0.015</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>200</td>
<td>0.0039</td>
<td>0.00039</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>250</td>
<td>0.001</td>
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</table>

In vitro, levofloxacin administered at 6 mg/kg or higher by rapid intravenous injection produced a statistically significant 95% CI for the microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

Table 18: Microbiologically Evaluable Efficacy Studies

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In mice, the posttherapy visit were 66.7% for levofloxacin and 60.6% for comparator. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0]. The microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

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In dogs, levofloxacin administered at 6 mg/kg or higher by rapid intravenous injection produced a statistically significant 95% CI for the microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

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In cats, the posttherapy visit were 66.7% for levofloxacin and 60.6% for comparator. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0]. The microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

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In pigs, the posttherapy visit were 66.7% for levofloxacin and 60.6% for comparator. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0]. The microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

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In rabbits, the posttherapy visit were 66.7% for levofloxacin and 60.6% for comparator. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0]. The microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

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In rats, the posttherapy visit were 66.7% for levofloxacin and 60.6% for comparator. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0]. The microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

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<tr>
<td>Klebsiella pneumoniae</td>
<td>16</td>
<td>2</td>
<td>0.015</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>200</td>
<td>0.0039</td>
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</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>250</td>
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In mice, the posttherapy visit were 66.7% for levofloxacin and 60.6% for comparator. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0]. The microbiological eradication rates at (cure plus improvement) with levofloxacin at 5 to 7 days posttherapy, the primary efficacy. The 95% CI for (levofloxacin minus comparator) was [-17.2, 12.0].

Table 26: Microbiologically Evaluable Efficacy Studies

<table>
<thead>
<tr>
<th>Organism</th>
<th>NDC</th>
<th>API</th>
<th>NTID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Escherichia coli</td>
<td>5</td>
<td>0.02</td>
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