AMIKACIN Sulfate Injection, USP

**URLS:**
1. AMIKACIN Sulfate Injection, USP
2. Wholesaler Item Numbers:
3. Storage Requirements:
4. Product Photo 1:
5. Product Photo 2:
6. Product Photo 3:
7. All Photos
8. All Photos
9. Package Insert Page:

**PDFS:**
10. Package Insert
12. SDS/MSDS Sheet
13. Barcodes
14. Return Goods Policy
WARNINGS

Patients treated with parenteral aminoglycosides should be under close clinical observation because of the potential ototoxicity and nephrotoxicity associated with their use. Safety for treatment periods which are longer than 14 days has not been established.

Neurotoxicity, manifested as vestibular and permanent bilateral auditory ototoxicity, can occur in patients with preexisting renal damage and in patients with normal renal function treated at higher doses and/or for periods longer than those recommended. The risk of aminoglycoside-induced ototoxicity is greater in patients with renal damage. High frequency deafness usually occurs first and can be detected only by audiometric testing. Vertigo may occur and may be evidence of vestibular injury. Other manifestations of neurotoxicity may include numbness, skin tingling, muscle twitching and convulsions. The risk of hearing loss due to aminoglycosides increases with the degree of exposure to either high peak or high trough serum concentrations. Patients developing cochlear damage may not have symptoms during therapy to warn them of developing eighth-nerve toxicity, and total or partial irreversible bilateral deafness may occur after the drug has been discontinued. Aminoglycoside-induced ototoxicity is usually irreversible.

Aminoglycosides are potentially nephrotoxic. The risk of nephrotoxicity is greater in patients with impaired renal function and in those who receive high doses or prolonged therapy.

Neuromuscular blockade and respiratory paralysis have been reported following parenteral injection, topical instillation (as in orthopedic and abdominal irrigation or in local treatment of empyema), and following oral use of aminoglycosides. The possibility of these phenomena should be considered if aminoglycosides are administered by any route, especially in patients receiving anesthetics, neuromuscular blocking agents such as tubocurarine, succinylcholine, decamethonium, or in patients receiving massive transfusions of citrate-anticoagulated blood. If blockage occurs, calcium salts may reverse these phenomena, but mechanical respiratory assistance may be necessary.

Renal and eighth-nerve function should be closely monitored especially in patients with known or suspected renal impairment at the onset of therapy and also in those whose renal function is initially normal but who develop signs of renal dysfunction during therapy. Serum concentrations of amikacin should be monitored when feasible to assure adequate levels and to avoid potentially toxic levels and prolonged peak concentrations above 35 micrograms per mL. Urine should be examined for decreased specific gravity, increased excretion of proteins, and the presence of cells or casts. Blood urea nitrogen, serum creatinine, or creatinine clearance should be measured periodically. Serial audiograms should be obtained where feasible in patients old enough to be tested, particularly high risk patients. Evidence of otoxicity (dizziness, vertigo, tinnitus, roaring in the ears, and hearing loss) or nephrotoxicity requires discontinuation of the drug or dosage adjustment.

Concurrent and/or sequential systemic, oral or topical use of other neurotoxic or nephrotoxic products, particularly bacitracin, cisplatin, amphotericin B, cephaloridine, paramomycin, viomycin, polymyxin B, colistin, vancomycin, or other aminoglycosides should be avoided. Other factors that may increase risk of toxicity are advanced age and dehydration.

The concurrent use of amikacin with potent diuretics (ethacrynic acid, or furosemide) should be avoided since diuretics by themselves may cause otoxicity. In addition, when administered intravenously, diuretics may enhance aminoglycoside toxicity by altering antibiotic concentrations in serum and tissue.
## AMIKACIN Sulfate Injection, USP

**WHOLESALER NUMBERS**

<table>
<thead>
<tr>
<th>Strength</th>
<th>ABC-STAR</th>
<th>ABC-SAP</th>
<th>Cardinal</th>
<th>HD Smith</th>
<th>Mckesson</th>
<th>Morris Dickson</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 mg per 2 mL</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>1 g per 4 mL</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.*
AMIKACIN Sulfate Injection, USP  STORAGE REQUIREMENTS

<table>
<thead>
<tr>
<th>NDC #25021</th>
<th>Strength</th>
<th>Storage Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>25021-173-02</td>
<td>500 mg per 2 mL</td>
<td>Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]</td>
</tr>
<tr>
<td>25021-173-04</td>
<td>1 g per 4 mL</td>
<td>Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]</td>
</tr>
</tbody>
</table>

*Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.*

The SAGENT logo, SAGENT and SAGENT Pharmaceuticals are registered trademarks of Sagent Pharmaceuticals, Inc.

© 2016 Sagent Pharmaceuticals, Inc.
*Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.
AMIKACIN Sulfate Injection, USP

*Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.
AMIKACIN Sulfate Injection, USP

*Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.

Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.
Please choose your desired package insert from the list(s) below:

<table>
<thead>
<tr>
<th>NDC #25021</th>
<th>Strength</th>
<th>Package Insert</th>
</tr>
</thead>
<tbody>
<tr>
<td>25021-173-02</td>
<td>500 mg per 2 mL</td>
<td></td>
</tr>
<tr>
<td>25021-173-04</td>
<td>1 g per 4 mL</td>
<td></td>
</tr>
</tbody>
</table>

*Please see full prescribing and safety information, including boxed warning, for AMIKACIN vials.

The SAGENT logo, SAGENT and SAGENT Pharmaceuticals are registered trademarks of Sagent Pharmaceuticals, Inc.

© 2016 Sagent Pharmaceuticals, Inc.
Amikacin Sulfate Injection, USP
(For Intramuscular or Intravenous Use)

**SAGIN®**

*Note: this is not a normal incidence test nor does it indicate the effectiveness of an antibiotic.*

**INDICATIONS AND USAGE**

Amikacin is a broad-spectrum antibiotic indicated for treatment of infections caused by susceptible strains of the designated organisms, as described below.

**Intramuscular Use:**
- Treatment of infections caused by susceptible organisms.
- Treatment of serious infections caused by susceptible strains of the following organisms: P. aeruginosa, E. coli, N. meningitidis, and other Gram-negative bacteria.

**Intravenous Use:**
- Treatment of infections caused by susceptible organisms, including serious infections caused by aerobic and anaerobic bacteria, such as P. aeruginosa, E. coli, and other Gram-negative bacteria.

**CONTRAINDICATIONS**

- Hypersensitivity to amikacin or other aminoglycosides.
- Known or suspected pre-existing hearing loss.

**WARNINGS**

- Hypersensitivity reactions, including anaphylaxis, can occur. Discontinue if symptoms develop.
- Neurotoxicity, ototoxicity, nephrotoxicity, and seizures can occur. Monitor for these effects.
- Intravascular administration has been associated with local tissue reactions. Avoid injecting directly into a vein or artery.
- Seizures have been reported in patients with renal impairment.

**ADVERSE REACTIONS**

- Gastrointestinal: Nausea, vomiting, diarrhea, abdominal pain, anorexia, constipation, electrolyte disturbances.
- Urogenital: Nephrotoxicity, ototoxicity, hearing loss, azotemia, hypokalemia, hypophosphatemia, hyperuricemia.
- Hematologic: Anemia, thrombocytopenia, leukopenia, neutropenia.
- Neurologic: Seizures, dizziness, paraesthesia, cranial nerve palsy, extrapyramidal reactions.
- Other: Hypersensitivity reactions, including anaphylaxis.

**DRUG INTERACTIONS**

- Amikacin may increase the risk of ototoxicity and nephrotoxicity when used with other nephrotoxic agents.

**PRECAUTIONS**

- Use with caution in patients with pre-existing hearing loss or renal impairment.
- Monitor for hearing loss, renal function, and hydration status.

**DOSAGE AND ADMINISTRATION**

- Intramuscular Injection: Usual dose is 500 mg to 1 g every 24 hours, depending on the severity of infection.
- Intravenous Injection: Usual dose is 500 mg to 1 g every 24 hours, depending on the severity of infection.

**HOW SUPPLIED**

- Sterile powder for intramuscular or intravenous injection.

**PATIENT INFORMATION**

- Amikacin should be used only by healthcare professionals who are experienced in its use.
- Patients should be instructed to report any symptoms of allergy or hypersensitivity.

**REFERENCES**


**NOMENCLATURE**

- For a list of abbreviations and symbols used in this monograph, see the inside back cover.
AMIKACIN

Easily distinguished on the shelf

Packaging Solutions are SupportIV℠

- Available in 500 mg per 2 mL single-dose vials and 1 g per 4 mL vials
- Features PreventIV Measures℠ Packaging and Labeling, designed to help reduce the risk of medication errors
- Full-color cartons coordinate with vial labels and caps
- Drug name and strengths are easy to read
- Preservative-free, AP rated, bar coded and not made with natural rubber latex

AMIKACIN Sulfate Injection, USP

Please see full prescribing information, including boxed warning, for AMIKACIN Sulfate Injection, USP, enclosed.

Every SAGENT® Product Features...

PreventIV Measures™ Packaging and Labeling

SAGENT Pharmaceuticals
Discover Injectables Excellence®
AMIKACIN Sulfate Injection, USP

INDICATIONS AND USAGE
Amikacin Sulfate Injection, USP is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species, Escherichia coli, species of indole-positive and indole-negative Proteus, Providencia species, Klebsiella-Enterobacter-Serratia species, and Acinetobacter (Mima-Herellea) species.

IMPORTANT SAFETY INFORMATION

WARNINGS
Patients treated with parenteral aminoglycosides should be under close clinical observation because of the potential ototoxicity and nephrotoxicity associated with their use. Safety for treatment periods which are longer than 14 days has not been established.

Neurotoxicity, manifested as vestibular and permanent bilateral auditory ototoxicity, can occur in patients with preexisting renal damage and in patients with normal renal function treated at higher doses and/or for periods longer than those recommended. The risk of aminoglycoside-induced ototoxicity is greater in patients with renal damage. High frequency deafness usually occurs first and can be detected only by audiometric testing. Vertigo may occur and may be evidence of vestibular injury. Other manifestations of neurotoxicity may include numbness, skin tingling, muscle twitching and convulsions. The risk of hearing loss due to aminoglycosides increases with the degree of exposure to either high peak or high trough serum concentrations. Patients developing cochlear damage may not have symptoms during therapy to warn them of developing eighth-nerve toxicity, and total or partial irreversible bilateral deafness may occur after the drug has been discontinued. Aminoglycoside-induced ototoxicity is usually irreversible.

Aminoglycosides are potentially nephrotoxic. The risk of nephrotoxicity is greater in patients with impaired renal function and in those who receive high doses or prolonged therapy.

Neuromuscular blockade and respiratory paralysis have been reported following parenteral injection, topical instillation (as in orthopedic and abdominal irrigation or in local treatment of empyema), and following oral use of aminoglycosides. The possibility of these phenomena should be considered if aminoglycosides are administered by any route, especially in patients receiving anesthetics, neuromuscular blocking agents such as tubocurarine, succinylcholine, decamethonium, or in patients receiving massive transfusions of citrate-anticoagulated blood. If blockage occurs, calcium salts may reverse these phenomena, but mechanical respiratory assistance may be necessary.

Renal and eighth-nerve function should be closely monitored especially in patients with known or suspected renal impairment at the onset of therapy and also in those whose renal function is initially normal but who develop signs of renal dysfunction during therapy. Serum concentrations of amikacin should be monitored when feasible to assure adequate levels and to avoid potentially toxic levels and prolonged peak concentrations above 35 micrograms per mL. Urine should be examined for decreased specific gravity, increased excretion of proteins, and the presence of cells or casts. Blood urea nitrogen, serum creatinine, or creatinine clearance should be measured periodically. Serial audiograms should be obtained where feasible in patients old enough to be tested, particularly high risk patients. Evidence of ototoxicity (dizziness, vertigo, tinnitus, roaring in the ears, and hearing loss) or nephrotoxicity requires discontinuation of the drug or dosage adjustment.

Concurrent and/or sequential systemic, oral or topical use of other neurotoxic or nephrotoxic products, particularly bacitracin, cisplatin, amphotericin B, cephaloridine, paromomycin, viomycin, polymyxin B, colistin, vancomycin, or other aminoglycosides should be avoided. Other factors that may increase risk of toxicity are advanced age and dehydration.

The concurrent use of amikacin with potent diuretics (ethacrynic acid, or furosemide) should be avoided since diuretics by themselves may cause ototoxicity. In addition, when administered intravenously, diuretics may enhance aminoglycoside toxicity by altering antibiotic concentrations in serum and tissue.

CONTRAINDICATIONS
A history of hypersensitivity to amikacin is a contraindication for its use. A history of hypersensitivity or serious toxic reactions to aminoglycosides may contraindicate the use of any other aminoglycoside because of the known cross-sensitivities of patients to drugs in this class.

WARNINGS
• Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycosides cross the placenta and there have been several reports of total irreversible, bilateral congenital deafness in children whose mothers received streptomycin during pregnancy.
• Amikacin Sulfate Injection contains sodium metabisulfite, a sulfite that may cause anaphylactic reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.
• Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Amikacin Sulfate Injection, USP, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. difficile.
• If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

PRECAUTIONS
• Prescribing amikacin 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.
• Aminoglycosides are quickly and almost totally absorbed when they are applied topically, except to the urinary bladder, in association with surgical procedures.
Irreversible deafness, renal failure, and death due to neuromuscular blockade have been reported following irrigation of both small and large surgical fields with an aminoglycoside preparation.

- **Amikacin Sulfate Injection, USP** is potentially nephrotoxic, ototoxic and neurotoxic. The concurrent or serial use of other ototoxic or nephrotoxic agents should be avoided either systemically or topically because of the potential for additive effects.
- Increased nephrotoxicity has been reported following concomitant parenteral administration of aminoglycoside antibiotics and cephalosporins.
- Since amikacin is present in high concentrations in the renal excretory system, patients should be well hydrated to minimize chemical irritation of the renal tubules.
- Elderly patients may have reduced renal function which may not be evident in routine screening tests such as BUN or serum creatinine. A creatinine clearance determination may be more useful. Monitoring of renal function during treatment with aminoglycosides is particularly important.
- Aminoglycosides should be used with caution in patients with muscular disorders such as myasthenia gravis or parkinsonism since these drugs may aggravate muscle weakness because of their potential curare-like effect on the neuromuscular junction.
- Cross-allergenicity among aminoglycosides has been demonstrated.
- It is not known whether amikacin is excreted in human milk. Many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from amikacin, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- Aminoglycosides should be used with caution in premature and neonatal infants because of the renal immaturity of these patients and the resulting prolongation of serum half-life of these drugs.

### ADVERSE REACTIONS

- All aminoglycosides have the potential to induce auditory, vestibular, and renal toxicity and neuromuscular blockade (see **WARNINGS** box). They occur more frequently in patients with present or past history of renal impairment, of treatment with other ototoxic or nephrotoxic drugs, and in patients treated for longer periods and/or with higher doses than recommended.
- **Neurotoxicity-Ototoxicity:** Toxic effects on the eighth cranial nerve can result in hearing loss, loss of balance, or both. Amikacin primarily affects auditory function. Cochlear damage includes high frequency deafness and usually occurs before clinical hearing loss can be detected.
- **Neurotoxicity-Neuromuscular Blockade:** Acute muscular paralysis and apnea can occur following treatment with aminoglycoside drugs.
- **Nephrotoxicity:** Elevation of serum creatinine, albuminuria, presence of red and white cells, casts, azotemia, and oliguria have been reported. Renal function changes are usually reversible when the drug is discontinued. As would be expected with any aminoglycoside, reports of toxic nephropathy and acute renal failure have been received during postmarketing surveillance.
- In addition to those described above, other adverse reactions which have been reported on rare occasions are skin rash, drug fever, headache, paresthesia, tremor, nausea and vomiting, eosinophilia, arthralgia, anemia, hypotension anemia, hypotension and hypomagnesemia. Macular infarction sometimes leading to permanent loss of vision has been reported following intravitreous administration (injection into the eye) of amikacin.

### OVERDOSAGE

In the event of overdosage or toxic reaction, peritoneal dialysis or hemodialysis will aid in the removal of amikacin from the blood. In the newborn infant, exchange transfusion may also be considered.

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 **AMIKACIN Sulfate Injection, USP.**
Amikacin Sulfate Injection, USP

(For Intramuscular or Intravenous Use)

**SAFIN**

- Inhibits the development of drug-resistant bacteria and maintains the effectiveness of the amikacin and other antituberculous drugs, as well as dapsone, for the treatment of tuberculosis which in about 15 days has not been established.

- May be used in the treatment of infections caused by susceptible strains of these organisms. The effectiveness of this drug in treating tuberculosis has not been established.

**WARNINGS**

- Patients with renal impairment should be on usual monitoring and not receive intravenous therapy. The effectiveness of this drug in treating tuberculosis has not been established.

- Meticillin-resistant staphylococci may be resistant. The effectiveness of this drug in treating tuberculosis has not been established.

- Sodium content may be considered when selecting the appropriate dose for patients with renal impairment.

**INDICATIONS AND USAGE**

- Amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.

- In patients with tuberculosis, amikacin is indicated for the treatment of tuberculosis caused by susceptible strains of Mycobacterium tuberculosis. The effectiveness of the drug has not been established.
Section 1 - Identification

(a) **Product Identifier:** Amikacin Sulfate Injection, USP

(b) **Product Code:** 25021-173, 25021-173
   - **Common/Trade Name:** N/A
   - **Chemical Name:** 0-3-amino-3-deoxy-a-D-glucopyranosyl-(1#4)-O-[6-amino-6-deoxy-a-D-glucopyranosyl-(1#6)]-N3-(4-amino-L-2-hydroxybutyryl)-2-deoxy-Lstreptamine sulfate (1:2)
   - **Chemical Family:** Aminoglycoside Antibiotic

(c) **Product Use:** Short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species, Escherichia coli, species of indole-positive and indole-negative
   - **Product Type:** Regulated Prescription Drug
   - **Container Information:** Pre-filled glass vial

(d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600

(e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

(a) **Classification:** U.S. OSHA
   - **Classification:** Possible Sensitizer
     - **Target Organ Toxin:** Possible Irritant

(b) **Signal Word,**
   **Hazard statement(s),**
   **Symbol(s), and/or**
   **Precautionary statement(s):**
   - **Hazard Statements:** Aminoglycosides may cause potential ototoxicity and nephrotoxicity, as well as fetal harm, allergic-type reactions, and associate diarrhea. Please reference package insert for additional information.
   - **Precautionary statements:** P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

(c) **Description of Hazards:** N/A

(d) **Unknown Acute Toxicity:** N/A
Section 3 – Composition / Information on Ingredients

500 mg/2 mL vial and 1g/ 4mL vial contains per each mL:

<table>
<thead>
<tr>
<th>(a) Chemical Name</th>
<th>(b) Common Name / Synonym</th>
<th>% Composition or other measure</th>
<th>(c) CAS No.</th>
<th>(d) Impurities / Stabilizing Additives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin Sulfate</td>
<td>Amikacin Sulfate</td>
<td>21.12</td>
<td>39831-55-5</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium Citrate Dihydrate</td>
<td>Sodium Citrate Dihydrate</td>
<td>2.048</td>
<td>18996-35-5</td>
<td>N/A</td>
</tr>
<tr>
<td>Sodium Metabisulfite</td>
<td>Sodium Metabisulfite</td>
<td>.54</td>
<td>7681-57-4</td>
<td>N/A</td>
</tr>
<tr>
<td>Water for injection</td>
<td>Water</td>
<td>76.14</td>
<td>7732-18-5</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Section 4 - First Aid Measures

Eye Exposure: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Injection: N/A

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.
Section 5 – Fire-fighting Measures

(a) Extinguishing Media
Use extinguishing agent suitable for type of surrounding fire. Water spray, Carbon Dioxide, Halon, Foam, Dry Chemical, and any “ABC” Class extinguishers.

(b) Hazardous Combustion Products:
None anticipated for this aqueous product

(c) Special Protective Equipment / Precautions:
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 - Accidental Release Measures

Spill:
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Release to Air: N/A
Release to Water: N/A
Section 7 - Handling and Storage

General Handling: No special handling required under conditions of normal product use.

Storage Conditions: Store at 20°C to 25°C (68°F to 77°F). For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin</td>
<td>OSHA</td>
<td>PEL</td>
<td>Not available</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
<td>Not available</td>
</tr>
<tr>
<td>Sodium citrate dehydrate</td>
<td>OSHA</td>
<td>PEL</td>
<td>Not available</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
<td>Not available</td>
</tr>
<tr>
<td>Sodium metabisulfite</td>
<td>OSHA</td>
<td>PEL</td>
<td>Not available</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Water for injection</td>
<td>OSHA</td>
<td>PEL</td>
<td>Not available</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
<td>Not available</td>
</tr>
</tbody>
</table>

(b) Engineering Controls

Ventilation: N/A
(c) Individual Protection Measures

<table>
<thead>
<tr>
<th>Protection Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Protection:</td>
<td>Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.</td>
</tr>
<tr>
<td>Eye Protection:</td>
<td>Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended</td>
</tr>
<tr>
<td>Skin Protection:</td>
<td>If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.</td>
</tr>
<tr>
<td>Other Protective Equipment:</td>
<td>N/A</td>
</tr>
<tr>
<td>Additional Exposure Precautions:</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Section 9 - Physical and Chemical Properties

| (a) Appearance | Liquid; Colorless to light straw |
| (b) Odor | N/A |
| (c) Odor Threshold | N/A |
| (d) pH | 4.5 (3.5 to 5.5) |
| (e) Melting Point | N/A |
| (f) Initial Boiling Point | N/A |
| (g) Flash Point | N/A |
| (h) Evaporation Rate | N/A |
| (i) Flammability | N/A |
| (j) Upper Lower Flammability or Explosion Limits | N/A |
| (k) Vapor Pressure | N/A |
| (l) Vapor Density | N/A |
| (m) Relative Density | N/A |
| (n) Solubility(ies) | N/A |
| (o) Partition Coefficient: n-octanol/water | N/A |
| (p) Auto-ignition Temperature | N/A |
| (q) Decomposition Temperature | N/A |
| (r) Viscosity | N/A |

### Section 10 - Stability and Reactivity

| (a) Reactivity | Not determined |
| (b) Chemical Stability | Stable under standard use and storage conditions. |
| (c) Possibility of Hazardous Reactions | Not determined |
| (d) Conditions to Avoid | Not determined |
| (e) Incompatible Materials | Not determined |
Section 11 - Toxicological Information

(a) Likely Routes of Exposure
Injection, Ingestion, skin, eye

(b) Symptoms related to the physical, chemical and toxicological characteristics
Injection: Local redness, swelling and/or pain; Flu-like symptoms, dizziness, loss of balance and hearing loss
Skin: redness, itching burning, skin damage
Eyes: stinging, watering, redness, swelling
See package insert for more information.

(c) Delayed and immediate effects and also chronic effects from short and long term exposure
Primary health effects include irritation of eyes and skin, and local swelling after injection (See above symptoms)
Chronic overexposure: may cause damage to hearing, kidneys and nervous system
See package insert for more information.

(d) Acute Toxicity

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amikacin Sulfate</td>
<td>LD$_{50}$</td>
<td>Oral</td>
<td>Mouse, Rat, Rabbit</td>
<td>$&gt;10,679$ mg/Kg, $&gt;4000$ mg/Kg, $&gt;3000$ mg/Kg</td>
</tr>
<tr>
<td>Amikacin Sulfate</td>
<td>LD$_{50}$</td>
<td>Intravenous</td>
<td>Mouse, Rat, Rabbit, Dog</td>
<td>$181$ mg/Kg, $234$ mg/Kg, $248$ mg/Kg, $383$ mg/Kg</td>
</tr>
<tr>
<td>Sodium Citrate</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

(e) Hazardous Chemical Listings
NTP: No       IARC: No       OSHA: No
Section 12 - Ecological Information

(a) Ecotoxicity  
(b) Persistence and degradability  Not determined for product.  
(c) Bioaccumulative potential  Not determined for product.  
(d) Mobility in soil  Not determined for product.  
(e) Other Adverse Effects  Not determined for product.  

Section 13 - Disposal Considerations

Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

Section 14 - Transport Information

(a) UN Number  N/A  
(b) UN Proper Shipping Name  N/A  
(c) Transport Hazard Class(es)  N/A  
(d) Packing Group  N/A  
(e) Environmental Hazards  N/A  
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)  N/A  

(g) Special Precautions  N/A  

DOT: Not regulated  
IMDG: Not regulated  
ICAO/ IATA: Not regulated
Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

**U.S. Regulations:**
- TSCA: No
- CERCLA: Not on this list
- SARA 302: Not on this list
- SARA 313: Not on this list

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>American Conference of Governmental Industrial Hygienists</td>
</tr>
<tr>
<td>AICS</td>
<td>Australian Inventory of Chemical Substances</td>
</tr>
<tr>
<td>AIHA</td>
<td>American Industrial Hygiene Association</td>
</tr>
<tr>
<td>ANSI</td>
<td>American National Standards Institute</td>
</tr>
<tr>
<td>CAS Number</td>
<td>Chemical Abstract Service Registry Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>Comprehensive Environmental Response Compensation and Liability Act (of 1980)</td>
</tr>
<tr>
<td>CHAN</td>
<td>Chemical Hazard Alert Notice</td>
</tr>
<tr>
<td>CHEMTREC</td>
<td>Chemical Transportation Emergency Center</td>
</tr>
<tr>
<td>DOT</td>
<td>Department of Transportation</td>
</tr>
<tr>
<td>DSL</td>
<td>Domestic Substances List</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td>EINECS</td>
<td>European Inventory of Existing Commercial Chemical Substances</td>
</tr>
<tr>
<td>ELINCS</td>
<td>European List of Notified Chemical Substances</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System of Classification and Labelling of Chemicals</td>
</tr>
<tr>
<td>HEPA</td>
<td>High Efficiency Particulate Air (Filter)</td>
</tr>
<tr>
<td>HMIS</td>
<td>Hazardous Materials Identification System</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer</td>
</tr>
<tr>
<td>ICAO/IATA</td>
<td>International Civil Aviation Organization/International Air Transport Association</td>
</tr>
<tr>
<td>IMO</td>
<td>International Maritime Organization</td>
</tr>
<tr>
<td>KOW</td>
<td>Octanol/Water Partition Coefficient</td>
</tr>
<tr>
<td>LEL</td>
<td>Lower Explosive Limit</td>
</tr>
<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet</td>
</tr>
<tr>
<td>MSHA</td>
<td>Mine Safety and Health Administration</td>
</tr>
<tr>
<td>NA</td>
<td>Not Applicable, except in Section 14 where NA = North America</td>
</tr>
<tr>
<td>NE</td>
<td>Not Established</td>
</tr>
<tr>
<td>NADA</td>
<td>New Animal Drug Application</td>
</tr>
<tr>
<td>NAIIF</td>
<td>No Applicable Information Found</td>
</tr>
<tr>
<td>NCI</td>
<td>National Cancer Institute</td>
</tr>
<tr>
<td>NDSL</td>
<td>Non-Domestic Substances List</td>
</tr>
<tr>
<td>NFPA</td>
<td>National Fire Protection Association</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>NPDES</td>
<td>National Pollutant Discharge Elimination System</td>
</tr>
<tr>
<td>NOS</td>
<td>Not Otherwise Specified</td>
</tr>
<tr>
<td>NTP</td>
<td>National Toxicology Program</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>OEL</td>
<td>Occupational Exposure Limit</td>
</tr>
<tr>
<td>PEL</td>
<td>Permissible Exposure Limit (OSHA)</td>
</tr>
<tr>
<td>RCRA</td>
<td>Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RQ</td>
<td>Reportable Quantity</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety Data Sheet</td>
</tr>
<tr>
<td>STEL</td>
<td>Short Term Exposure Limit</td>
</tr>
<tr>
<td>TLV</td>
<td>Threshold Limit Value (ACGIH)</td>
</tr>
<tr>
<td>TPQ</td>
<td>Threshold Planning Quantity</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substances Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>Time Weighted Average/8 Hours Unless Otherwise Noted</td>
</tr>
<tr>
<td>UEL</td>
<td>Upper Explosive Limit</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
</tr>
<tr>
<td>WEEL</td>
<td>Workplace Environmental Exposure Level (AIHA)</td>
</tr>
<tr>
<td>WHMIS</td>
<td>Workplace Hazardous Materials Information System</td>
</tr>
</tbody>
</table>
## AMIKACIN Sulfate Injection, USP

<table>
<thead>
<tr>
<th></th>
<th>Individual Vial (RSS-Limited)</th>
<th>Carton of Vials (GS1-128)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC #25021-173-02</td>
<td><img src="image1" alt="Barcode" /></td>
<td><img src="image2" alt="Barcode" /></td>
</tr>
<tr>
<td>500 mg per 2 mL</td>
<td><img src="image3" alt="Barcode" /></td>
<td><img src="image4" alt="Barcode" /></td>
</tr>
<tr>
<td>NDC #25021-173-04</td>
<td><img src="image5" alt="Barcode" /></td>
<td><img src="image6" alt="Barcode" /></td>
</tr>
<tr>
<td>1 g per 4 mL</td>
<td><img src="image7" alt="Barcode" /></td>
<td><img src="image8" alt="Barcode" /></td>
</tr>
</tbody>
</table>

Click here for Important Product Safety Information

Package Insert

Copyright (C) 2016 Sagent Pharmaceuticals, Inc.
Prior Authorization:

Prior authorization from Sagent Pharmaceuticals, or Sagent, in the form of a Returned Goods Authorization (RGA), is required for all product returns. Prior authorization and issuance of credit is subject to the below terms and conditions. Sagent’s only authorized return facility is located at 4580 Mendenhall Road, Memphis, TN 38141 (“Sagent Memphis”). Sagent is not responsible for product shipping cost or other charges for products returned to a facility other than Sagent Memphis.

Please contact Sagent customer service department at 866-625-1618 for RGA assistance.

Return Shipment Instructions:

Returned products must contain a packing list with customer account information and debit memo (RGA) number clearly designated. Use only one debit memo (RGA) number per return shipment. If a return shipment is multiple boxes, photocopy paperwork with debit memo (RGA) number and place in each box. It is suggested that the return be insured and records kept. Sagent is not responsible for return shipments prior to receipt by Sagent Memphis.

All pre-authorized returns, evidenced by an RGA, must be sent to the following address:

Sagent Pharmaceuticals
4580 Mendenhall Road
Memphis, TN 38141

Returnable Items:

- Product must be within six (6) months prior to and twelve (12) months post expiration.
- Product must have a VALID Sagent lot number and expiry date.
- Product must be in original, unaltered container/trade package.

Conditions for Returned Goods Credit:

- A valid Return Goods Authorization (RGA) Number must accompany all returns for proper credit.
- RGA Numbers are valid for 90 days from issuance. Expired RGA Numbers will be considered invalid and no credit will be issued.
• All returned product must be received at Sagent Memphis within 90 days of RGA issuance to receive credit. Products that have been destroyed by customers or agent of customer will not receive credit.
• Partial will not be accepted.
• Product must not be damaged by fire, smoke, heat, water, acts of God or be returned as the result of bankruptcy proceedings.
• Product must not be damaged by improper handling, storage or shipping.
• Product must not require refrigeration.
• Packages must not be marked or disfigured in any way.
• Reimbursement price will be based on the lower of the customer’s original purchase price or current price.
• Sagent will issue an eighty-percent (80%) credit allowance based on the lower of the customer’s original purchase price or current price.
• Credit will be allowed toward future purchases of any Sagent products. Credits from returned goods are valid for one (1) year from the date of issuance.
• Returns totaling fifty dollars ($50.00) or less are not eligible for credit.
• Product must be returned by the customer who purchased the product from Sagent. Credit will be issued to customer’s account.
• Returned products will be verified by Sagent and the final credit will be calculated based upon Sagent’s count.

Shipping Errors/Damaged Shipments:

Products shipped in error by Sagent are subject to 100% replacement credit if reported to Sagent within ten (10) days of receipt and returned to Sagent in original condition within 25 days of receipt. Products damaged in transit are subject to 100% replacement credit if reported to Sagent within ten (10) working days of receipt and returned to Sagent within 25 days of receipt. Contact Sagent Customer Service at 866-625-1618 to report shipping errors or damaged shipments.

Return Transportation Charges:

Prepaid by customer except when return is due to shipping error or products damaged in transit.

Terms of Return Policy:

• Product(s) returned to the wholesaler/distributor by their customer(s) are not returnable to Sagent.
• Sagent will not reimburse customer costs relating to third-party returns, destruction charges, shipping costs or processing.
• All returns are subject to review by Sagent. Issuance of RGA does not guarantee credit. Credit issuance is dependent on confirmed receipt/review of return goods.
• Returns made to Sagent or its agent without prior approval, as evidenced by a Sagent RGA, will be destroyed and credit will not be issued.
• Sagent may, at its discretion, make exceptions to the returned goods policy based upon extenuating circumstances.

Revised on 10/17/07
Non-Returnable Items/no credit:

- Non-authorized products.
- Products with more than six (6) months dating.
- Opened products or products not in original containers/packaging.
- Product purchased as close-outs or other special pricing, e.g., free goods or short-dated promotions.
- Shipments received with concealed damages not reported within 10 days of receiving the shipment.
- Items not properly stored as outlined by the Prescription Drug Marketing Act.
- Private label, repackaged products or products not in the original Sagent container.
- Products discontinued for more than 12 months.
- Product for which proof of purchase cannot be verified.
- Products returned outside of this policy will not receive credit.

Product Recall:

Should a product recall or withdrawal be necessary, Sagent will compensate its customers only for the reasonable expense incurred in performing all recall services requested by Sagent.

Other:

Sagent Pharmaceutical reserves the right to impose a handling fee on all returned goods. Federal law prohibits our representatives from transporting products between accounts or picking-up returns. Sagent reserves the right to inspect all authorized returns prior to issuing credit and to destroy products deemed unfit for sale.