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
AMIKACIN Sulfate Injection, USP

**Innovator Product Name: AMIKIN®**
*(Amikin is a registered trademark of Bristol-Myers Squibb Company.)*

<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>
</tr>
</thead>
<tbody>
<tr>
<td>25021-173-02</td>
<td>Glass Vial</td>
<td>500 mg</td>
<td>2 mL</td>
<td>250 mg per mL</td>
<td>13 mm</td>
<td>10 Vials</td>
<td>✓</td>
</tr>
<tr>
<td>25021-173-04</td>
<td>Glass Vial</td>
<td>1 g</td>
<td>4 mL</td>
<td>250 mg per mL</td>
<td>13 mm</td>
<td>10 Vials</td>
<td>✓</td>
</tr>
</tbody>
</table>

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.

**AMIKACIN Sulfate Injection, USP**

**INDICATIONS AND USAGE**


**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 otoxicity 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 otoxicity 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 allergic-type 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.

(continued on next page)
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.
- Aminoglycosides should not be given concurrently with potent diuretics.
- 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 Intraoperative Use)