Tobramycin in 0.9% Sodium Chloride Injection

60 mg Tobramycin in 50 mL
80 mg Tobramycin in 100 mL

For INTRAVENOUS INFUSION ONLY
Flexible Container

NORMAL DOSAGE

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, after reconstitution and container permit. See CONTRAINDICATIONS.

DOSAGE AND ADMINISTRATION

Tobramycin in 0.9% Sodium Chloride Injection is supplied in a single-dose flexible container as follows:

<table>
<thead>
<tr>
<th>Size</th>
<th>Tobramycin Sulfate (mg/mL)</th>
<th>50 mL</th>
<th>100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>60 mg</td>
<td>1.2</td>
<td>0.8</td>
<td>1.2</td>
</tr>
<tr>
<td>80 mg</td>
<td>1.6</td>
<td>1.2</td>
<td>1.6</td>
</tr>
</tbody>
</table>

Precautions: See Appendix B. See Appendix C for Appendix C. Concerns about use in specific populations, particularly in premature or low birth weight infants, should be evaluated in the context of the patient's clinical condition and the severity of the problem being treated.

Tobramycin in 0.9% Sodium Chloride Injection is a colorless sterile aqueous solution for parenteral administration.

Tobramycin sulfate, a water-soluble antibiotic of the aminoglycoside group, is derived from the Streptomyces species. Tobramycin in 0.9% Sodium Chloride Injection is a ready-to-use isotonic solution. NO DILUTION OR RECONSTITUTION IS NECESSARY.

Normal dosage or prolonged therapy: If the creatinine clearance rate is not available and the patient's condition is stable, a dosage frequency of 8 hours may be determined by dividing the average daily dose from Table 2 by 0.75 (multiply the normal dose from Table 2 by the percent of normal renal function from the accompanying nomogram). An adjustment guide for determining reduced dosage is shown in Appendix B. If serum creatinine levels are less than 4 mg/100 mL, the amount of the reduced dose can be determined by multiplying the normal daily dose with 0.75.

Intravenous Administration

For intravenous administration, the usual volume of 50 to 100 mL is administered over 20 to 30 minutes. For children, the dose can be made by removing and discarding the appropriate amount from either unit.

Peak urine concentrations ranging from 75 to 100 µg/mL have been observed following the intramuscular injection of a single dose of 1 mg/kg. After seven days of treatment, the amount of tobramycin recovered in the urine after parenteral administration is approximately 60% of the dose administered.

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Printed in USA
Hospira, Inc., Lake Forest, IL 60085 USA

EN-2854

Approved for FDA Submission L. Kindwald 09/07/11

Reference ID: 305881
Susceptibility Test Results

When available, the clinical microbiology laboratory should provide cumulative results of the in vitro susceptibility test results for antibiotics normally used in resident hospitals to the physician as periodic reports that describe the susceptibility profiles of nosocomial and community-acquired pathogens. These reports should be the physician in selecting the most effective antimicrobial.

For laboratories that do not perform susceptibility testing, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) is a mandatory requirement before certification. The result of this survey should include the susceptibility of clinical isolates to antibiotics used in the hospital. This information is essential for the physician in selecting the most effective antimicrobial. The following is a list of situations where a high dosage of drug can be used. This category also provides a buffer zone, which may be necessary to during therapy. When available, the clinical microbiology laboratory should provide cumulative results of the in vitro susceptibility test results for antibiotics normally used in resident hospitals to the physician as periodic reports that describe the susceptibility profiles of nosocomial and community-acquired pathogens. These reports should be the physician in selecting the most effective antimicrobial.

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Tobramycin is a glycopeptide antibiotic that is used to treat infections caused by susceptible bacteria. Its mechanism of action is similar to that of other aminoglycosides, such as gentamicin and amikacin. Tobramycin is administered intravenously and is available in various formulations, including intravenous solutions, powders for reconstitution, and tablets.

**INDICATIONS AND USES**

Tobramycin is indicated for the treatment of serious infections caused by susceptible strains of bacteria. It is also used to treat infections caused by susceptible strains of Pseudomonas aeruginosa, Klebsiella pneumoniae, Enterobacter aerogenes, Escherichia coli, Proteus mirabilis, and other Enterobacteriaceae. It is also used to treat infections caused by susceptible strains of Serratia, Citrobacter, and other members of the Enterobacteriaceae family.

**CONTRAINDICATIONS**

Tobramycin is contraindicated in patients with a history of hypersensitivity to aminoglycosides or other aminoglycosides. It is also contraindicated in patients with a history of renal impairment or failure, polycystic kidney disease, or any other condition that may impair renal function.

**WARNINGS**

**Neurotoxicity**

Tobramycin may cause irreversible bilateral deafness in children whose mothers received streptomycin during pregnancy. In patients with renal impairment, tobramycin should be discontinued. Sometimes after starting treatment with tobramycin, patients can develop high-tone hearing loss. This condition should be monitored periodically during therapy. To prevent prolonged concentrations above normal, patients should be instructed to take the medication exactly as prescribed.

**Reactions**

The most common adverse reactions associated with the use of tobramycin are hypotension, tinnitus, vertigo, tinnitus, and hearing loss. Other reactions include nephrotoxicity, ototoxicity, and myelosuppression.

**Pharmacokinetics**

Tobramycin is administered intravenously and is available in various formulations, including intravenous solutions, powders for reconstitution, and tablets. It is rapidly absorbed from the intravenous route and reaches peak serum concentrations within 1-2 hours. The elimination half-life of tobramycin is approximately 2-3 hours in patients with normal renal function. The drug is primarily excreted unchanged in the urine. The volume of distribution is approximately 10 liters/kg.

**DOSAGE AND ADMINISTRATION**

The usual dosage is 1-2 mg/kg/day, given in two or three equal doses, with a maximum daily dose not to exceed 4 mg/kg. The dosage should be adjusted according to the patient's renal function. In patients with impaired renal function, the dosage should be reduced accordingly. In patients with end-stage renal disease, tobramycin should be administered in doses ranging from 0.25 to 0.5 mg/kg/day.

**Storage**

Tobramycin is stable at room temperature for up to 30 days. It should be stored at room temperature and protected from light.

**Teratogenicity**

Tobramycin is teratogenic in animals and should be used only in women who are not pregnant. It is not known whether tobramycin is teratogenic in humans.

**Nursing Considerations**

Patients receiving tobramycin should be monitored for potential adverse effects, especially nephrotoxicity and ototoxicity. The patient should be assessed for the presence of risk factors for nephrotoxicity, such as pre-existing renal disease, dehydration, and diuretic therapy.

**Patient Education**

Patients should be instructed to take the medication exactly as prescribed and to complete the full course of treatment. They should be informed of the potential for hearing loss and be advised to notify their healthcare provider if they experience any hearing changes.

**Laboratory Considerations**

Tobramycin is not a substrate for the human placenta. It does not cross the placenta and is not transplacentally transferred to the fetus. Therefore, it is not a concern for the use of tobramycin in pregnant women.

**Toxicology**

Tobramycin is not expected to cause significant toxicity in humans. However, it is important to monitor patients for potential adverse effects, such as nephrotoxicity and ototoxicity, especially in those with pre-existing renal or hearing loss.

**ADVERSE REACTIONS**

Tobramycin is well tolerated and is generally safe when used according to the recommended dosage and precautions. The most common adverse reactions associated with the use of tobramycin are nephrotoxicity and ototoxicity. Other less common adverse reactions include fever, chills, rash, and headache.

**MECHANISM OF ACTION**

Tobramycin is a glycopeptide antibiotic that inhibits bacterial protein synthesis by binding to 30S ribosomal subunits, thereby preventing the formation of functional 70S ribosomes.

**CLINICAL PHARMACOLOGY**

Tobramycin is rapidly absorbed from the intravenous route and reaches peak serum concentrations within 1-2 hours. The elimination half-life of tobramycin is approximately 2-3 hours in patients with normal renal function. The drug is primarily excreted unchanged in the urine. The volume of distribution is approximately 10 liters/kg.

**PREGNANCY AND NURSING**

Tobramycin is contraindicated in pregnancy. It is not known whether tobramycin is teratogenic in humans. It is not known whether tobramycin is excreted in human milk. However, because many drugs are excreted in human milk, caution should be exercised when tobramycin is administered to a woman who is nursing.

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