Tobramycin Injection, USP

INDICATIONS AND USAGE:

Tobramycin is indicated for the treatment of infections caused by susceptible strains of the designated pathogens listed in the INDICATIONS AND USAGE section above.

DOSAGE AND ADMINISTRATION:

The dosage or dosage interval adjusted according to the patient's renal function. Recommended dosages are included in Table 1. Do not administer more than 1 mg/kg/min because of the risk of ototoxicity and nephrotoxicity. The dose of tobramycin may be administered every 8 hours or as a single daily dose of 10 to 20 mg/kg.

When pediatric patients are to receive tobramycin in combination with other drugs administered for longer periods or at higher doses than those recommended, other drugs should be administered at their usual dosage schedules or administered according to institutional practice.

TOBRAMYCIN is contraindicated in patients with a known sensitivity to it or to any of the ingredients of the formulation.

ADVERSE REACTIONS:

The most common adverse reactions associated with the use of tobramycin are nausea, vomiting, diarrhea, constipation, abdominal pain, cramping, and flatulence. Other adverse reactions reported include rash, pruritus, urticaria, fever, chills, general malaise, and pruritus.

OVERDOSAGE:

The usual signs and symptoms of toxicity are neurotoxicity and nephrotoxicity. Overdosage of tobramycin usually occurs when the drug is administered over a longer period than indicated or in higher doses than those recommended. Overdosage may also occur in patients with impaired renal function. The symptoms of overdosage include nausea, vomiting, diarrhea, abdominal pain, cramping, and flatulence. Overdosage may also be associated with central nervous system effects such as dizziness, drowsiness, and ataxia. CNS symptoms may be greater in patients receiving concomitant therapy with other neurotoxic agents such as bacitracin or polymyxin.

To treat overdosage, stop the administration of tobramycin immediately. Appropriate fluid and electrolyte management should be instituted. In cases of severe overdosage, hemodialysis may be beneficial. Nephrotoxicity is the most serious form of overdose. In cases of severe overdosage, hemodialysis may be beneficial. Nephrotoxicity is the most serious form of overdose. In cases of severe overdosage, hemodialysis may be beneficial.
Tobramycin is an aminoglycoside antibiotic with activity against many Gram-negative bacteria. It is indicated for the treatment of serious infections caused by susceptible strains of bacteria. Tobramycin acts by inhibiting the synthesis of bacterial protein, thereby preventing the bacteria from reproducing. The drug is eliminated primarily through the kidneys and may be used in patients with renal impairment. Tobramycin is available in intravenous and oral formulations and is used to treat a variety of bacterial infections, including infections of the respiratory tract, skin, and urinary tract. It is important to monitor patients treated with tobramycin for signs of nephrotoxicity and ototoxicity, as these adverse effects can occur with long-term or high-dose use of the medication.
Tobramycin may be administered at 8-hour intervals or with normal doses given at prolonged intervals. Both of these methods are suggested as guides to be used in conjunction with the following nomogram (see WARNINGS and PRECAUTIONS).

**DOSAGE AND ADMINISTRATION:**
Tobramycin Injection, USP may be given intramuscularly or intravenously. Recommended dosages are given in Table 3. The patient's pretreatment trough serum concentrations should be monitored during therapy. Peak concentrations may result in reduced serum concentrations of amino glycosides. Measurement of tobramycin serum concentrations is advisable when the patient's pretreatment trough serum concentrations are not available or cannot be measured directly. They are based on the creatinine clearance of the serum creatinine of the patient. Because these values correlate with the half-life of tobramycin, the dosage may be adjusted directly in patients with cystic fibrosis, an initial dosing regimen of 3 mg/kg/day is suggested. This dosing schedule is used in conjunction with careful clinical and laboratory observations of the patient and should be modified as needed. Further methods should be applied to the dosage schedule derived from these values.

**Reduced Dosage at 8-Hour Intervals:** When the creatinine clearance is less than 50 mL per minute, or when the serum creatinine value is known, the amount of the reduced dose can be determined by multiplying the normal dose from the accompanying nomogram.

**Nomogram:** A rough guide for determining reduced dosage at 8-hour intervals for patients whose serum creatinine values are known. To divide the normally recommended dose by the patient’s serum creatinine.

**Dosage in Obese Patients:** The appropriate dose may be calculated by using the patient’s estimated lean body weight on which to figure the dosage.

**Intermittent Administration:** Tobramycin should be administered by withdrawing the appropriate dose from a suitable diluent.

**Intravenous Administration:** For intravenous administration, the usual volume of diluent is 0.9% Sodium Chloride Injection or 5% Dextrose Injection. Tobramycin Injection, USP may be given intramuscularly or intravenously. Recommended dosages are given in Table 3. The patient’s pretreatment trough serum concentrations should be monitored during therapy. Peak concentrations may result in reduced serum concentrations of amino glycosides. Measurement of tobramycin serum concentrations is advisable when the patient’s pretreatment trough serum concentrations are not available or cannot be measured directly. They are based on the creatinine clearance of the serum creatinine of the patient. Because these values correlate with the half-life of tobramycin, the dosage may be adjusted directly in patients with cystic fibrosis, an initial dosing regimen of 3 mg/kg/day is suggested. This dosing schedule is used in conjunction with careful clinical and laboratory observations of the patient and should be modified as needed. Further methods should be applied to the dosage schedule derived from these values. A rough guide for determining reduced dosage at 8-hour intervals for patients whose serum creatinine values are known. To divide the normally recommended dose by the patient’s serum creatinine.

**Dosage in Obese Patients:** The appropriate dose may be calculated by using the patient’s estimated lean body weight on which to figure the dosage.

**Intermittent Administration:** Tobramycin should be administered by withdrawing the appropriate dose from a suitable diluent.

**Intravenous Administration:** For intravenous administration, the usual volume of diluent is 0.9% Sodium Chloride Injection or 5% Dextrose Injection. Tobramycin Injection, USP may be given intramuscularly or intravenously. Recommended dosages are given in Table 3. The patient’s pretreatment trough serum concentrations should be monitored during therapy. Peak concentrations may result in reduced serum concentrations of amino glycosides. Measurement of tobramycin serum concentrations is advisable when the patient’s pretreatment trough serum concentrations are not available or cannot be measured directly. They are based on the creatinine clearance of the serum creatinine of the patient. Because these values correlate with the half-life of tobramycin, the dosage may be adjusted directly in patients with cystic fibrosis, an initial dosing regimen of 3 mg/kg/day is suggested. This dosing schedule is used in conjunction with careful clinical and laboratory observations of the patient and should be modified as needed. Further methods should be applied to the dosage schedule derived from these values.