WARNINGS

Patients treated with aminoglycosides should be under close clinical observation because of the potential toxicity associated with their use.

As with other aminoglycosides, gentamicin injection is potentially nephrotoxic. The risk of nephrotoxicity is greater in patients with impaired renal function and in those who receive high dosage of prolonged therapy.

Neurotoxicity manifested by oto toxicity, both vestibular and auditory, can occur in patients treated with gentamicin, primarily in those with preexisting renal damage and in patients with normal renal function treated with higher doses and/or for longer periods than recommended. Aminoglycoside-induced oto toxicity is usually reversible if it occurs. Manifestations of neurotoxicity may include numbness, skin tingling, muscle twitching and convulsions.

Renal and eighth cranial nerve function should be closely monitored, especially in patients with known or suspected reduced renal function at onset of therapy and also in those whose renal function is initially normal but who develop signs of renal dysfunction during therapy. Urine should be examined for decreased specific gravity, increased excretion of protein and the presence of cells or casts. Blood urea nitrogen (BUN), serum creatinine or creatinine clearance should be determined periodically. When feasible, it is recommended that serial audiograms be obtained in patients old enough to be tested, particularly high-risk patients. Evidence of ototoxicity (dizziness, vertigo, tinnitus, roaring in the ears or hearing loss) or neurotoxicity requires dosage adjustment or discontinuation of the drug. As with other aminoglycosides, on rare occasions changes in renal and eighth cranial nerve function may not become manifest until soon after completion of therapy.

Serum concentrations of aminoglycosides should be monitored when feasible to assure adequate levels and to avoid potentially toxic levels. When monitoring gentamicin trough concentrations, dosage should be adjusted so that peak levels above 12 mcg/mL are avoided. When monitoring gentamicin trough concentrations, dosage should be adjusted so that levels above 2 mcg/mL are avoided. Excessive peak and/or trough serum concentrations of aminoglycosides may increase the risk of renal and eighth cranial nerve toxicity.

In the event of overdosage or toxic reactions, hemodialysis may aid in the removal of gentamicin from the blood, especially if the renal function is, or becomes, compromised. The rate of removal of gentamicin is considerably lower by peritoneal dialysis than it is by hemodialysis.

In the newborn infant, exchange transfusions may also be considered. Concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs, such as cisplatin, cephaloridine, kanamycin, amikacin, neomycin, polymyxin B, colistin, paromomycin, streptomycin, tobramycin, vancomycin, and viomycin, should be avoided. Other factors which may increase patient risk of toxicity are advanced age and hearing loss. In severely burned patients, the half-life may be significantly decreased and resulting serum levels may be lower than anticipated from the mg/kg dose.

Probenecid does not affect renal tubular transport of gentamicin. The endogenous creatinine clearance rate and the serum creatinine level have a high correlation with the half-life of gentamicin in serum. Results of these tests may serve as guides for adjusting dosage in patients with renal impairment (see DOSAGE AND ADMINISTRATION).

Following parenteral administration, gentamicin can be detected in serum, lungs, tissues, spumum, and bile. Gentamicin sulfate, a water-soluble antibiotic of the genus Micromonospora purpurea, is an actinomycete. It has the following structural formula.

Gentamicin injection is a sterile, nonpyrogenic aqueous solution for parenteral administration. Each mL contains: Gentamicin sulfate equivalent to 40 mg gentamicin, methylparaben 1.8 mg and propylparaben 0.2 mg as preservatives, sodium sulfite 3.2 mg and edetate disodium 0.1 mg. Water for Injection q.s. Sodium hydroxide and/or sulfuric acid may have been added for pH adjustment.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Gentamicin Injection, USP and other antibacterial drugs, Gentamicin Injection, USP should be used only to treat or prevent infections that are known or strongly suspected to be caused by bacteria.

CLINICAL PHARMACOLOGY

After intramuscular (IM) administration of gentamicin sulfate, peak serum concentrations usually occur between 30 and 60 minutes and serum levels are measured up to 12 hours. Gentamicin is administered by intravenous (IV) infusion over a two-hour period, the serum concentrations are similar to those obtained by IM administration.

In patients with normal renal function, peak serum concentrations of gentamicin (mcg/mL) are usually up to four times the single IM dose (mg/kg); for example, a 1 mg/kg injection in adults may be expected to yield a peak concentration of up to 4 mcg/mL; a 1.5 mg/kg dose may produce levels up to 6 mcg/mL. While some variation is to be expected due to age, weight, temperature, surface area and physiologic differences, the individual patient given the same dose twice should have similar peak levels. Gentamicin administered at 1 mg/kg every eight hours for the usual 7 to 10 day treatment period to patients with normal renal function does not accumulate in the serum.

Gentamicin, like all aminoglycosides, may accumulate in serum and tissues of patients treated with higher doses and/or for prolonged periods, particularly in the presence of impaired renal function. In adult patients, treatment with gentamicin, even at dosages of 4 mg/kg/day or higher for 7 to 10 days may result in a slight, progressive rise in both peak and trough concentrations. In patients with impaired renal function, gentamicin is cleared from the serum at a slower rate than in patients with the normal renal function. The more severe the impairment, the slower the clearance. (Dosage must be adjusted.) Some degree of redistribution into extra-cellular fluid, peak serum concentrations may be lower than usual in adult patients who have a large volume of distribution. Concentrations of gentamicin in febrile patients may be lower than those in afebrile patients given the same dose. When body temperature returns to normal, serum concentrations of the drug may rise. Febrile and anemic states may be associated with a shorter than usual serum half-life. (Dosage adjustment is usually not necessary.) In severely burned patients, the half-life may be significantly decreased and resulting serum concentrations may be lower than anticipated from the mg/kg dose.

Gentamicin administered at 1 mg/kg every two hours, the serum concentrations are measurable for six to eight hours. When gentamicin is administered at 1 mg/kg every two hours, the serum concentrations are measurable for six to eight hours.

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To reduce the development of drug-resistant bacteria and maintain the effectiveness of Gentamicin Injection, USP and other antibacterial drugs, Gentamicin Injection, USP should be used only to treat or prevent infections that are known or strongly suspected to be caused by bacteria.

Microbiology

In vitro tests have demonstrated that gentamicin is a bactericidal antibiotic which acts by inhibiting protein synthesis. It is highly toxic to susceptible microorganisms. It is active against a wide variety of pathogenic bacteria, including gram-negative and gram-positive species, (indole-positive and indole-negative), Pseudomonas aeruginosa, species of the Klebsiella-Enterobacter-Serratia group, Citrobacter species.
and Staphylococcus species (including penicillin- and cephalosporin-resistant strains). Gentamicin is also active in vitro against species of Salmonella and Shigella. The following bacteria are usually resist- ent to the aminoglycosides: Pseudomonas aeruginosa, most species of streptococci, particularly group D and anaerobic organisms, as well as Bacteroides species and Peptostreptococcus species.

In vitro studies have shown that an aminoglycoside concentration of 10 mcg/ml is sufficient to inhibit growth of most strains of Gram-negative bacteria. During initiation of cell wall synthesis may act synergistically against many of these strains. This effect is most pronounced with gentamicin and ampicillin, carbencillin, nafcillin or oxacillin.

The combined effect of gentamicin and carbencillin is synergistic, whereas the combined effect of gentamicin and ampicillin is additive. The best synergism comes with the combination of gentamicin and ampicillin, which has been shown to be bactericidal against some strains of Pseudomonas aeruginosa.

Gentamicin may be active against clinical iso- mates of bacteria resistant to other aminoglycosides. Bacteria resistant to one aminoglycoside may be resistant to one or more aminoglycosides. Bacterial resistance to gentamicin is generally developed slowly.

Susceptibility Testing
If the disc method of susceptibility testing is used that described by Bauer et al. (Am J Clin Path 45:493, 1966; 49:25-29, 1968), a disc containing 10 mcg of gentamicin should be placed on the surface of the inoculated petri dish with a zone diameter of 12 mm or more considered to be indicative of susceptible organism. A zone of less than 15 mm is indicative of resistance. In certain clinical situations, additional susceptibility testing by the tube or agar dilution method; gentamicin substance is available for this purpose.

INDICATIONS AND USAGE:
To treat infections caused by drug-resistant bacteria and maintain the effectiveness of Gentamicin Injection, USP and other antibiotic drugs, Gentamicin Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, this information should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of antibiotics.

Gentamicin Injection, USP is indicated in the treatment of serious infections caused by susceptible aerobic, anaerobic, and non-aerobic, non-pathogenic flora. Pseudomonas aeruginosa, Proteus species (including indole-positive and indole-negative), Escherichia coli, Klebsiella species, and Citrobacter species and Staphylococcus species (coagulase-positive and coagulase-negative)

Clinical selection of gentamicin injection to be effective in bacterial neonatal sep- sис, bacterial septicemia and serious bacterial infections affecting the urinary bladder (except urinary bladder), the respiratory tract, gastrointestinal tract, or other soft tissue (including burns). Aminoglycosides, includ- ing gentamicin, are not indicated in uncomplicated infantile gastroenteritis unless the causative organisms are susceptible to these antibiotics and are not susceptible to antibiotics having less toxicity.

Specimens for bacterial culture should be obtained to identify and characterize the causative organ- ism and determine their susceptibility to gentamicin.

Gentamicin injection may be considered as initial therapy for infections caused by susceptible anaerobic, non-anaerobic, and non-antibiotic-resistant infections, and therapy may be instituted before obtaining results of susceptibility testing. The decision to use the antibiotic drug should be based on the results of susceptibility tests, the severity of the infection and the additional administration of the drug. SEE §8 WARNINGS. If the causative organisms are resistant to ampicillin, another appropriate therapy should then be considered.

In serious infections when the causative organ- ism is not known or when the causative organ- ism may be administered as initial therapy in conjunction with a penicillin-type or cephalosporin-type drug before obtaining results of susceptibility tests of the anaerobic organisms are suspected to be etiologic agents, consideration should be given to using other appropriate therapy in addition to con- tinuation of gentamicin. Following identification of the organism and its susceptibility, appropriate antibacterial therapy should then be continued.

Gentamicin injection has been used effectively in conjunc- tion with other antibacterial agents in the treatment of life-threatening infections caused by Pseudomonas aeruginosa. It has also been used successfully in the treatment of endocarditis caused by Staphylococcus aureus and Staphylococcus epidermidis. Gentamicin injection has also been shown to be effective in the treatment of serious staphy- lococcal infec- tions. While not the antibiotic of first choice, gentamicin injection may be considered in the presence of penicillin-resistant anaerobic and intracerebrovascu- lar infections caused by susceptible strains of staphylo- coccus and gram-negative organisms.

Infections in which gram-positive bacteria sepsis or staphylococcal pneumonia, a penicillin-type drug is also usually indicated as concomitant therapy.

CONTRAINDICATIONS:
Hypersensitivity to gentamicin is a contraindication to its use. A history of hypersensitivity or serious toxicity reactions to other aminoglyco- sides may contraindicate use of gentamicin because of the known cross-reactivity of patients to drugs in this class.

WARNINGS:
(See boxed WARNINGS)
Contains sodium metabasulite, a salt that may cause exacerbation of hypokalemia and hypomagnesemia in patients with normal renal function who did not receive streptomy- cillin during pregnancy. Serious side effects to mothers, newborn or fetus may be observed after birth of infants to mothers who received gentamicin during pregnancy. If the causative organisms are resist- ant to gentamicin, other appropriate therapy should be based on the results of susceptibility testing. The antibiotic may be irreversible. Hearing loss is usually manifested initially by diminution of high-tone acuity. Other factors which may increase the risk of toxicity include excessive dosage, dehydration and pre- vious exposure to other ototoxic drugs.

Peripheral edema, anemia, skin, alopecia, general weakness, including numbness, skin tingling, muscle twitching, convulsions and a myasthenia gravis-like syndrome should be considered.

NOTE: The risk of toxic reactions is low in patients with normal renal function who did not receive gentamicin injection, USP for 48 hours or for longer periods of time than recommended.

Other reported adverse reactions possibly related to gentamicin injection, USP include nausea, vomit- ing, diarrhea, abdominal pain, dyspepsia, anemia, rash, angioedema, urticaria, fever, headache, sweating, malaise, burning, laryngeal edema, anaphylactoid reactions, fever and head ache, nausea, vomiting, mild to severe renal failure, anemia, leukopenia, eosinophilia, peripheral neuropathy, or encephalopathy, which has been associated with hypomagnesemia, hypokalemia and hypocalcemia. While clinical laboratory test results may reflect these changes, no specific laboratory test results can be considered diagnostic of this condition.

Laboratory abnormalities possibly related to gentamicin injection, USP have included increased serum lactic dehydrogenase (LDH), bilirubin, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), serum alkaline phosphatase (SAP), serum creatine phosphokinase, serum creatinine, serum cholesterol, serum sodium, serum chloride, serum calcium, serum potassium; anemia, leukopenia, granulocy- tosis, eosinophilia, polycythemia, neutropenia, lymphopenia, transient agranulocytosis, eosinophilia, anemia, thrombocytopenia, transient agranulocytosis, eosinophilia, and increased and decreased reticulocyte counts and thrombocytopenia. Since these abnormalities may be isolated findings, they may also be associated with clinically related signs and symptoms. Transient and potentially irreversible weakness may be associated with hypomagnesemia, hypokalemia and hypocalcemia.

When clinical laboratory test results have been abnormal, generally, therapy has been discontinued. There have been occasional reports of pain at the injection site. Subcutaneous administration of gentamicin sulfate at higher doses or for longer periods than recommended has been reported.

Some bacterial isolates resistant to gentamicin may result in overgrowth of nonsusceptible organisms. If this occurs, appropriate therapy should be instituted.

Additional WARNINGS regarding concurrent use of poison diuretics and regarding concurrent and sequential use of other neurotoxic and/or for other essential information.

Information for Patients
Patients should be counseled that antibiotic drugs may not only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When using an antibiotic drug to treat a bacterial infection, patients should be told that although it is common to feel better in a few days after starting therapy, the entire course of treatment (especially if diuresis is required) and in patients treated for longer periods or with larger doses than recommended.

Neurotoxicity
Serious adverse effects on both vestibular and auditory branches of the eighth nerve have been reported in patients receiving gentamicin injection, USP (especially if hemodialysis is required) and in patients on high doses and/or prolonged therapy (e.g., chronic renal failure, Sny- nuresis, roaring in the ears and also hearing loss, which may be irreversible. Hearing loss is usually manifested initially by diminution of high-tone acuity. Other factors which may increase the risk of toxicity include excessive dosage, dehydration and previous exposure to other ototoxic drugs.

Peripheral edema, anemia, skin, alopecia, general weakness, including numbness, skin tingling, muscle twitching, convulsions and a myasthenia gravis-like syndrome should be considered.

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Laboratory abnormalities possibly related to gentamicin injection, USP have included increased serum lactic dehydrogenase (LDH), bilirubin, decreased serum calcium, magnesium, sodium and, potassium; anemia, leucopenia, neutropenia, transient agranulocytosis, eosinophilia, anemia, thrombocytopenia, transient agranulocytosis, eosinophilia, and increased and decreased reticulocyte counts and thrombocytopenia. Since these abnormalities may be isolated findings, they may also be associated with clinically related signs and symptoms. Transient and potentially irreversible weakness may be associated with hypomagnesemia, hypokalemia and hypocalcemia.

With the rare occurrence of gentamicin sulfate is generally rare, there has been an occasional report of pain at the injection site. Subcu- taneous administration of gentamicin sulfate at higher doses or for longer periods than recommended has been reported.

OVERDOSE:
In the event of overdose or toxic reactions, hemodialysis may aid in the removal of gentamicin from the blood, especially if renal function is, or becomes, impaired. The removal of gentamicin is considerably lowered by peritoneal dialysis than by hemodialysis.

DOSAGE AND ADMINISTRATION:
Gentamicin injection, USP is given by IV. The usual treatment body weight should be obtained for calculation of correct dosage. The dosage should be based on an estimate of the lean body mass. It is desirable to limit the duration of treatment with gentamicin injection, USP to shorter periods than recommended.
PATIENTS WITH NORMAL RENAL FUNCTION

Adults
The recommended dosage of gentamicin injection for patients with serious infections and normal renal function is 3 mg/kg/day, administered in three equal doses every eight hours (Table I).

For patients with life-threatening infections, dosages up to 5 mg/kg/day may be administered in three or four equal doses. This dosage should be reduced to 3 mg/kg/day as soon as clinically indicated (Table I).

It is desirable to measure both peak and trough serum concentrations of gentamicin to determine the adequacy and safety of the dosage. When such measurements are feasible, they should be carried out periodically during therapy to assure adequate but not excessive drug levels. For example, the peak concentration (at 30 to 60 minutes after IM injection) is expected to be in the range of 4 to 6 mcg/mL. When monitoring peak concentrations after IM or IV administration, dosage should be adjusted so that prolonged levels above 12 mcg/mL are avoided. When monitoring trough concentrations or in a sterile solution for the next dose), dosage should be adjusted so that levels above 2 mcg/mL are avoided. Determination of the adequacy of a serum level for a particular patient must take into consideration the susceptibility of the causative organism, the severity of the infection and the status of the patient’s host-defense mechanisms.

In patients with extensive burns, altered pharmacokinetics may result in reduced serum concentrations of aminoglycosides. In such patients treated with gentamicin, measurement of serum concentrations is recommended as a basis for dosage adjustment.

**TABLE I**

**DOSEAGE SCHEDULE FOR PATIENTS WITH NORMAL RENAL FUNCTION**

(Dosage at Eight-Hour Intervals)


<table>
<thead>
<tr>
<th>Patient’s Weight (lb)</th>
<th>Dose for Life-Threatening Infections (Reduce Weight)</th>
<th>Dose for Serious Infections (mg/kg/day)</th>
<th>Usual Dose for Clinically Indicated Infections (mg/kg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>45</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>50</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>55</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>60</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>65</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>70</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>75</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>80</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>85</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>90</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>95</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
<tr>
<td>100</td>
<td>0.1 mcg/mL</td>
<td>1.7 mg/kg</td>
<td>0.1 mcg/mL</td>
</tr>
</tbody>
</table>

The recommended dosage of gentamicin injection for patients with serious infections and normal renal function is 3 mg/kg/day, administered in three equal doses every eight hours (Table I).

**TABLE II**

**DOSEAGE ADJUSTMENT GUIDE FOR PATIENTS WITH RENAL IMPAIRMENT**

(Dosage at Eight-Hour Intervals After the Usual Initial Dose)


<table>
<thead>
<tr>
<th>Serum Creatinine (mg %)</th>
<th>Approximate Dose for Life-Threatening Infections (mg/kg/day)</th>
<th>Approximate Dose for Serious Infections (mg/kg/day)</th>
<th>Usual Dose for Clinically Indicated Infections (mg/kg/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1.1</td>
<td>&gt; 100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>1.1-1.3</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>1.4-1.6</td>
<td>55-100</td>
<td>55-100</td>
<td>55-100</td>
</tr>
<tr>
<td>1.7-1.9</td>
<td>45-55</td>
<td>45-55</td>
<td>45-55</td>
</tr>
<tr>
<td>2.2-2.4</td>
<td>40-45</td>
<td>40-45</td>
<td>40-45</td>
</tr>
<tr>
<td>2.5-3.0</td>
<td>35-45</td>
<td>35-45</td>
<td>35-45</td>
</tr>
<tr>
<td>3.0-4.0</td>
<td>30-50</td>
<td>30-50</td>
<td>30-50</td>
</tr>
<tr>
<td>4.0-6.0</td>
<td>25-25</td>
<td>25-25</td>
<td>25-25</td>
</tr>
<tr>
<td>6.0-8.0</td>
<td>20-20</td>
<td>20-20</td>
<td>20-20</td>
</tr>
<tr>
<td>8.0-10.0</td>
<td>15-20</td>
<td>15-20</td>
<td>15-20</td>
</tr>
<tr>
<td>10.0-12.0</td>
<td>10-15</td>
<td>10-15</td>
<td>10-15</td>
</tr>
<tr>
<td>&gt; 12.0</td>
<td>&lt; 10</td>
<td>&lt; 10</td>
<td>&lt; 10</td>
</tr>
</tbody>
</table>

**Children**
6 to 7.5 mg/kg/day (2 to 2.5 mg/kg administered every four or five hours)

**Infants and Neonates**
7.5 mg/kg/day (2.5 mg/kg administered every eight hours)

**Premature or Full-Term Neonates One Week of Age or Less**
5 mg/kg/day (2.5 mg/kg administered every 12 hours)

For further information concerning the use of gentamicin in infants and children, see gentamicin injection (pediatric) product information. The usual duration of treatment for all patients is 7 to 10 days. In difficult and complicated infections, a longer course of therapy may be necessary. In such cases monitoring of renal, auditory and vestibular functions is recommended, since toxicity may occur more apt to occur with treatment extended for more than 10 days. Dosage should be reduced if clinically indicated.

**FOR INTRAVENOUS ADMINISTRATION**
The IV administration of gentamicin may be particularly useful for treating patients with bacterial septicemia or those in shock. It may also be the preferred route of administration for some patients with congestive heart failure, hematologic disorders, severe burns or those with reduced muscle mass. For intermittent IV administration in adults, a single dose of gentamicin injection may be diluted in 50 to 200 mL of sterile isotonic saline solution or in sterile solution of dextrose 5% in water; in infants and children, the volume of diluent should be less. The solution may be infused over a period of one-half to two hours.

The recommended dosage for IM and IV administration is identical.

Gentamicin injection should not be physically premixed with other drugs, but should be administered separately in accordance with the

**PATIENTS WITH IMPAIRED RENAL FUNCTION**

Dosage must be adjusted in patients with impaired renal function to assure therapeutically adequate, but not excessive blood levels. Whenever possible the serum concentration of gentamicin should be monitored. One method of dosage adjustment is to increase the interval between administration of the usual doses. Since the serum creatinine concentration has a high correlation with the serum half-life of gentamicin, this laboratory test may provide guidance for adjustment of the interval between doses. The interval between doses (in hours) may be approximated by multiplying the serum creatinine level (mg/100 mL) by 8. For example, a patient weighing 60 kg with a serum creatinine level of 2 mg/100 mL could be given 60 mg (1 mg/kg) every 14 hours (2 x 8).

In patients with serious systemic infections and renal impairment, it may be desirable to administer the antibiotic more frequently but in reduced dosage. In such patients, serum concentrations of gentamicin should be measured so that adequate but not excessive levels result. A peak and trough concentration measured intermittently during therapy will provide optimal guidance for adjusting dosage. After the usual initial dose, a rough guide for determining reduced dosage at eight-hour intervals is to divide the normally recommended dose by the serum creatinine level (Table II). For example, after an initial dose of 60 mg (1 mg/kg), a patient weighing 60 kg with a serum creatinine level of 2 mg/100 mL could be given 30 mg every eight hours (60 – 2). It should be noted that the status of renal function may change over the course of the infectious process.

It is important to recognize that deteriorating renal function may require a greater reduction in dosage than that specified in the above guidelines for patients with stable renal impairment.

**HOW SUPPLIED**
Gentamicin Injection, USP, containing gentamicin 40 mg/mL is supplied as follows:

**Product NDC No.**

| Gentamicin Injection (Pediatric), 10 mg/mL, supplied in 2 mL (20 mg) vials in packages of 25. |
| Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature). |

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