

PRODUCT MONOGRAPH

Pr GENTAMICIN INJECTION USP

Gentamicin base (as sulfate) USP

10 mg/mL and 40 mg/mL

Antibiotic

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PrGentamicin Injection USP
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10 mg/mL and 40 mg/mL

THERAPEUTIC CLASSIFICATION

Antibiotic

ACTIONS AND CLINICAL PHARMACOLOGY

Gentamicin is a bactericidal antibiotic which affects bacterial growth by specific inhibition of normal protein synthesis in susceptible bacteria.

INDICATIONS

Gentamicin is clinically effective in serious infections due to susceptible Gram-negative and Gram-positive bacteria, including: *Pseudomonas aeruginosa*, indole-negative and indole-positive *Proteus* species, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Serratia marcescens* and *Staphylococcus* species (including strains resistant to other antibiotics).

The use of gentamicin is indicated in the treatment of serious infections caused by laboratory determined susceptible bacteria, with due regard for relative antibiotic toxicity. Therefore, the drug should be considered for treatment of:

- bacteremia
- respiratory tract infections
- urinary tract infections
- infected wounds: surgical and traumatic
- bone and soft tissue infections, including peritonitis and burns complicated by sepsis.

In the majority of cases bacteriologic cultures should be obtained initially to identify the causative organism and to determine its sensitivity to gentamicin. Sensitivity discs of 10 mcg and 2 mcg are available for this purpose.

In suspected or documented Gram-negative septicemia, particularly when shock or hypotension are present, gentamicin should be considered for initial antimicrobial therapy. Gentamicin should also be considered in serious *Staphylococcus* infections when other conventional antimicrobial therapy is inappropriate or when bacterial susceptibility testing and clinical judgment indicate its use. If anaerobic organisms are suspected, additional antimicrobial therapy should be added to the gentamicin regimen.

The decision to continue therapy with gentamicin should be based on results of the sensitivity tests, clinical response of the patient, and consideration of relative antibiotic toxicity.

Clinical studies have shown that organisms previously sensitive to gentamicin have become resistant during therapy. Although this has occurred infrequently, the possibility should nevertheless be considered. There is evidence that cross resistance between gentamicin and aminoglycoside antibiotics may occur since bacteria made resistant to aminoglycoside antibiotics artificially in the laboratory are also resistant to gentamicin. However, gentamicin may be active against clinical isolates of bacteria resistant to other aminoglycosides. Conversely, organisms resistant to gentamicin may be sensitive to other aminoglycoside antibiotics.

If susceptibility tests indicate the causative organism is resistant to gentamicin, other tests or additional antimicrobial therapy should be instituted.

Combined therapy with gentamicin and a penicillin type of drug has been used in suspected sepsis until bacteriological studies have identified the etiological organism.

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 infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

CONTRAINDICATIONS

A history of hypersensitivity or toxic reactions to gentamicin are contraindications to its use.

Pregnancy and Lactation

Although studies in pregnant animals have not revealed teratogenic effects, gentamicin is not recommended during pregnancy except in life-threatening situations.

Aminoglycoside antibiotics cross the placenta and may cause fetal harm when administered to pregnant woman. There have been reports of total irreversible bilateral congenital deafness in children whose mothers received aminoglycosides, including gentamicin, during pregnancy. If gentamicin is used during pregnancy or if the patient becomes pregnant while taking gentamicin, she should be apprised of the potential hazard to the fetus.

In nursing mothers gentamicin is excreted in breast milk to a minimal degree. Because of the potential for serious adverse reactions from aminoglycosides in nursing infants, a decision should be made to discontinue nursing or therapy, taking into account the importance of the drug to the mother.

Newborns: Gentamicin should not be used in the newborn except for the treatment of life-threatening infections. Although follow-up in these cases has been limited, few adverse reactions have been revealed.

PRECAUTIONS

Ototoxicity: Gentamicin, in common with the antibiotics streptomycin, neomycin and kanamycin, has produced ototoxicity in experimental animals and man. This adverse reaction, which may be delayed in onset, is manifested primarily by damage to vestibular function. The reversibility of this adverse reaction is frequently contingent upon early recognition of potential ototoxicity. In all patients developing tinnitus, dizziness or loss of hearing, the attending physician should strongly consider discontinuing this antibiotic except in those cases where gentamicin appears to be the only proven course of therapy.

Complete damage has occurred mainly in patients who were uremic, had renal dysfunction, had prior therapy with ototoxic drugs or received higher doses and longer courses of therapy than those recommended.

In patients who have previously been treated with drugs likely to affect eighth cranial nerve function (e.g. streptomycin, neomycin, kanamycin, etc.) gentamicin should be used with caution and with the understanding that toxic effects may be cumulative with these agents.

Potent diuretics such as ethacrynic acid and furosemide have been associated with eighth cranial nerve dysfunction, and the concomitant use of either of these drugs with gentamicin should be avoided. It is believed that intravenous diuretics may cause fairly rapid rise in gentamicin serum levels and potentiate ototoxicity.

In patients with impaired renal function, the frequency of gentamicin administration should be reduced (see **DOSAGE AND ADMINISTRATION**), and renal function should be monitored along with evaluation of auditory and vestibular function. Serum concentrations of gentamicin should be monitored whenever feasible; prolonged concentrations above 12 mcg/mL should be avoided.

Nephrotoxicity: Nephrotoxicity manifested by an elevated blood urea nitrogen or serum creatinine level or a decrease in the creatinine clearance has been reported with gentamicin. In most cases, these changes have been reversible when the drug has been discontinued.

The administration of other potentially nephrotoxic agents prior to or in conjunction with gentamicin may increase the risk of nephrotoxicity.

Susceptibility/Resistance:

Development of Drug Resistant Bacteria: Prescribing Gentamicin Injection USP in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

Superinfection: As with other antibiotics, treatment with gentamicin may occasionally result in overgrowth of non-susceptible organisms. If superinfection occurs, appropriate measures should be taken.

Neuromuscular Blocking Action: Neuromuscular blockage and respiratory paralysis have been reported in the cat receiving high doses (40 mg/kg) of gentamicin. The possibility of these phenomena occurring in man should be considered if gentamicin is administered to patients receiving general anesthesia and/or neuromuscular blocking agents such as succinylcholine and tubocurarine.

In patients with myasthenia gravis, use of drugs with potential neuromuscular blocking action may be dangerous.

Neuromuscular blocking action produced by gentamicin in animals may be antagonized by neostigmine or calcium.

ADVERSE REACTIONS

In addition to the ototoxicity and nephrotoxicity discussed under **PRECAUTIONS**, other adverse reactions reported infrequently and possibly related to gentamicin include increased serum transaminase (SGOT, SGPT), increased reticulocyte count, increased serum bilirubin, anemia, rash, granulocytopenia, urticaria, thrombocytopenia, headache, vomiting and muscle twitching.

Adverse reactions reported rarely and possibly related to gentamicin are nausea, increased salivation, lethargy and decreased appetite, weight loss, pulmonary fibrosis, purpura, splenomegaly, transient hepatomegaly, itching, numbness, skin tingling, laryngeal edema and spasm, joint pain, drug fever, convulsions, hypotension, hypertension, decreased serum calcium, decreased hemoglobin and hematocrit, fifth nerve paresthesia and gastrointestinal hemorrhage. One case of neuromuscular blocking action has been reported in the literature.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

In the event of overdosage or toxic reactions, peritoneal dialysis or hemodialysis will aid in the removal of gentamicin from the blood. These procedures are of particular importance in patients with impaired renal function.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

Gentamicin Injection USP is usually given intramuscularly. The intravenous route generally is reserved for special indications (see **Intravenous Injection**).

Using the recommended doses, considerable variation in the serum concentration between individual patients has been observed. In order to insure adequate therapeutic concentration which may be critical, while at the same time avoiding potentially toxic concentrations, it is

desirable to measure peak and trough gentamicin serum concentrations. Following intravenous or intramuscular administration, 2 or 3 times daily, the peak concentration, measured 30 minutes to 1 hour after administration, is expected to be in the range of 4 to 6 mcg/mL. With once daily administration, transient, high peak concentrations can be anticipated. With all regimens, the dosages should be adjusted to avoid prolonged concentrations above 10 to 12 mcg/mL. Trough levels above 2 mcg/mL, measured just before the next dose, should also be avoided. Determination of the adequacy of a serum level for a particular patient must take into consideration susceptibility of the causative microorganism, severity of infection, and the status of the patient's host-defence mechanisms.

The usual duration of treatment for all patients is 7 to 10 days. In complicated infections, a longer course of therapy may be necessary. In such cases, monitoring of renal, auditory and vestibular functions is recommended, since toxicity is more likely to occur with treatment extended over 10 days. Dosage should be reduced if clinically indicated.

Intramuscular Injection

Patients with Normal Renal Function

Urinary Tract Infections: Gentamicin is highly concentrated in urine and renal tissue. In patients with lower urinary tract infection, particularly if chronic or recurrent and without evidence of impairment of renal function, Gentamicin Injection USP may be administered intramuscularly either in a dose of 160 mg once a day or 80 mg twice a day for 7 to 10 days. For adults weighing less than 60 kg, the single daily dose should be 3 mg/kg of body weight.

Upper urinary tract infections, such as pyelonephritis, and more particularly if there are signs of systemic involvement, should be treated according to one of the dosage schedules for systemic infections.

Since gentamicin activity is increased at pH 7.5, it may be advantageous to alkalinize the urine of patients for urinary tract infections.

Systemic Infections Adults: The recommended dosage of Gentamicin Injection USP for adult patients with serious infections and normal renal function is 3 mg/kg/day administered intramuscularly in three equal doses. Therefore, for patients weighing over 60 kg, the usual dosage is 80 mg three times daily. For patients weighing 60 kg or less, the usual dosage is 60 mg three times a day.

The usual duration of treatment 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 advisable.

Life-Threatening Infections In patients with life-threatening infections, dosages up to 5 mg/kg/day should be administered in three or four equally divided doses. This dosage should be reduced to 3 mg/kg/day as soon as clinically indicated.

Children: The precautions for the treatment of infection in children are the same as those for adults.

In severe infections, the recommended dosage is 3-6 mg/kg/day administered in three equal doses, every 8 hours. If a dosage greater than 3 mg/kg/day is administered initially, it should be reduced to 3 mg/kg/day when clinically indicated.

Infants and Neonates (see **CONTRAINDICATIONS**): In premature and full-term neonates, one week of age or less, a dosage of 6 mg/kg/day may be administered in two equal doses every 12 hours. In infants older than 1 week, gentamicin may be administered in 3 equal doses every 8 hours. Using the recommended doses, considerable variation in the serum levels between individual patients has been observed. In order to insure adequate therapeutic levels which may be critical, while at the same time avoiding potentially toxic concentrations, serum levels should be monitored. A serum level in excess of 10-12 mcg/mL following intramuscular administration should be considered potentially toxic.

The usual duration of treatment 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 advisable.

Intramuscular Injection

Patients with Impaired Renal Function

Dosage must be adjusted in patients with impaired renal function (see Table I). Since the creatinine clearance rate and serum creatinine concentration have high correlation with the serum half-life of gentamicin, these laboratory tests may provide the guidance necessary for adjustment of the interval between doses of Gentamicin Injection USP. The serum half-life (in hours) of gentamicin may be estimated by multiplying the serum creatinine (mg/100 mL) by four. The frequency of administration (in hours) may be approximated by doubling the serum half-life.

Table I: APPROXIMATE DOSAGE GUIDELINES FOR GENTAMICIN IN ADULT PATIENTS BASED ON RENAL FUNCTION

Body Weight Adult Patient	Dose	RENAL FUNCTION TESTS			
		Creatinine Clearance Rate (mL/min)	Serum Creatinine (mg %)	Blood Urea Nitrogen (mg %)	Frequency of Administration
Over 60 kg (132 lb)	80 mg (2 mL)	Over 70	Less than 1.4	Less than 18	Every 8 hours
		35 – 70	1.4 – 1.9	18 – 29	Every 12 hours
		24 – 34	2.0 – 2.8	30 – 39	Every 18 hours
		16 – 32	2.9 – 3.7	40 – 49	Every 24 hours
		10 – 15	3.8 – 5.3	50 – 74	Every 36 hours
		5 – 9	5.4 – 7.2	75 – 100	Every 48 hours
60kg or less (132 lb)	60 mg (1.5 mL)	Same as above			

In patients with renal failure who are undergoing 14-hour hemodialysis twice weekly, administration of gentamicin, 1 mg/kg, at the end of each dialysis period has been suggested.

In those instances when only a blood urea nitrogen (BUN) concentration is available, this value may be utilized initially, however, it should be supplemented with a serum creatinine level or creatinine clearance rate whenever possible.

This dosage schedule is not intended as a rigid recommendation but is provided as a guide in dosage when the measurement of gentamicin serum levels is not feasible. It should be used in conjunction with close clinical and laboratory observations of the patients and modified as deemed necessary by the treating physician.

Intravenous Injection

The intravenous administration of gentamicin is recommended in those circumstances when the intramuscular route is not feasible, e.g. patients in shock, with hemorrhagic disorders, severe burns, or reduced muscle mass.

The recommended dosage for intravenous administration is 3 mg/kg/day in three equally divided doses, identical to that recommended for intramuscular use.

For intravenous administration, a single dose (1 mg/kg) of Gentamicin Injection USP is diluted in 100-200 mL of 0.9% Sodium Chloride Injection or in 5% Dextrose Injection. The solution is infused over a period of one to two hours and repeated every eight hours, if necessary.

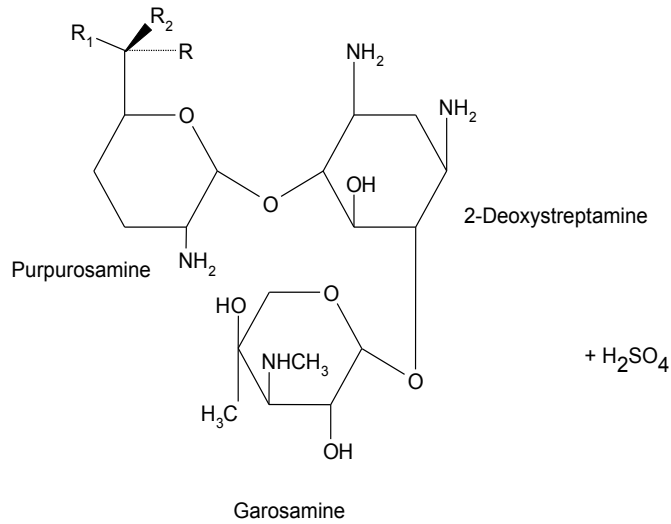
A single dose of Gentamicin Injection USP undiluted may also be given directly into the sidearm of an intravenous tubing set, slowly over a period of two to three minutes and repeated every eight hours, if necessary.

PHARMACEUTICAL INFORMATION

Drug Substance

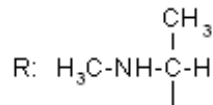
Proper Name: Gentamicin sulfate, USP

Structural Formula: Gentamicin is a mixture of the following three substances:



Chemical Name:

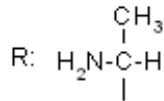
a) gentamicin C₁:



Molecular Formula: C₂₁H₄₃N₅O₇

Molecular weight (free base): 477.6 g/mol

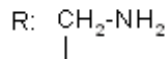
b) gentamicin C₂:



Molecular Formula: C₂₀H₄₁N₅O₇

Molecular weight (free base): 463.6 g/mol

c) gentamicin C_{1a}:



Molecular Formula: C₁₉H₃₉N₅O₇

Molecular weight (free base): 449.5 g/mol

The relative ratio of C₁ : C_{1a} : C₂ is variable in a range of 25-50 : 10-35 : 25-55%.

Description: White to buff powder. Soluble in water; insoluble in alcohol, acetone and benzene.

The pH of a 1:25 solution of gentamicin in water is 3.5-5.5.

Composition

Gentamicin Injection USP, 10 mg/mL: Each mL contains: gentamicin base USP (as sulfate) 10 mg, sodium bisulfite 1.625 mg, disodium edetate dihydrate 0.1 mg, water for injection and sodium hydroxide and/or sulfuric acid to adjust pH.

Gentamicin Injection USP, 40 mg/mL: Each mL contains: gentamicin base USP (as sulfate) 40 mg, methylparaben 1.8 mg, propylparaben 0.2 mg, sodium bisulfite 3.2 mg, disodium edetate dihydrate 0.1 mg, water for injection and sodium hydroxide and/or sulfuric acid to adjust pH.

Stability And Storage Recommendations

Store between 15 and 30°C. Protect from light.

Latex-free stoppers – Stoppers contain no dry natural rubber.

COMPATIBILITY

Gentamicin Injection USP should not be physically premixed with other drugs, but should be administered separately in accordance with the recommended route of administration and dosage schedule.

For intravenous administration Gentamicin Injection USP may be added to 0.9% Sodium Chloride Injection or 5% Dextrose Injection. Gentamicin Injection USP is compatible and stable for 24 hours when diluted to 0.35-0.7 mg/mL with either 0.9% Sodium Chloride Injection or Dextrose Injection 5%. The diluted infusion mixture should be prepared immediately before use and any portion not used within 24 hours must be discarded.

As with all parenteral drug products, intravenous admixtures should be inspected visually for clarity, particulate matter, precipitation, discoloration and leakage prior to administration whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discoloration or leakage should not be used.

AVAILABILITY OF DOSAGE FORMS

Gentamicin Injection USP, 10 mg/mL, is available in 2 mL single use vials, boxes of 10. Discard unused portion.

Gentamicin Injection USP, 40 mg/mL, is available in 2 mL and 20 mL multidose vials, boxes of 10 and 1, respectively. Discard 28 days after initial use.

MICROBIOLOGY

Gentamicin is active against a wide variety of pathogenic Gram-negative and Gram-positive bacteria: *Pseudomonas aeruginosa*, *Proteus* species (both indole-positive and indole-negative), *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Serratia marcescens* and *Staphylococcus* species (including penicillin and methicillin-resistant strains) (see Table II).

In addition, gentamicin is active *in vitro* against certain species of *Streptococcus* (see Table II). Only minimal activity has been found against *Streptococcus faecalis* and *S. pneumoniae*. Most anaerobes (species of *Clostridium*, *Bacteroides*, and *Diphtheroids*) are resistant.

The bactericidal concentration of gentamicin is usually one to four times the minimal inhibitory concentration. Gentamicin was over eight times more active *in vitro* at pH 7.5 than at pH 5.5 against several urinary pathogens.

Table II: SENSITIVITY (*IN VITRO*) OF CLINICALLY IMPORTANT BACTERIA TO GENTAMICIN SULFATE

Species of Bacteria	Number of Strains Tested	Number & Percent (%) of Strains Inhibited by Two Concentrations of Gentamicin			
		5 mcg/mL or less		10 mcg/mL or less	
<i>Klebsiella-Enterobacter-Serratia</i>	2113	1912	(91%)	2064	(98%)
<i>Klebsiella pneumoniae</i>	1062	1023	(96%)	1046	(98%)
<i>Enterobacter aerogenes</i>	131	123	(94%)	131	(100%)
<i>Serratia marcescens</i>	175	163	(93%)	174	(99%)
Not specified	745	603		713	
<i>Escherichia</i> species	2124	1775	(84%)	1961	(92%)
<i>E. coli</i>	2024	1675	(83%)	1861	(92%)
Not specified	100	100		100	
<i>Staphylococcus</i> species	1640	1582	(96%)	1596	(97%)
<i>S. albus</i>	15	15	(100%)	15	(100%)
<i>S. aureus</i>	1450	1395	(96%)	1409	(97%)
Not specified	175	172		172	
(Methicillin-resistant <i>S. aureus</i>)	(21)	(21)		(21)	
<i>Streptococcus</i> species	344	176	(51%)	211	(61%)
<i>S. faecalis</i>	179	69	(39%)	97	(54%)
<i>S. pyogenes</i>	116	86	(74%)	95	(82%)
<i>S. agalactiae</i>	3	3	(100%)	3	(100%)
<i>S. flavus</i>	1	1	(100%)	1	(100%)
Not specified	45	17		25	
<i>Pseudomonas aeruginosa</i>	2027	1667	(83%)	1952	(96%)
<i>Proteus</i> species (including indole-positive and indole-negative)	1487	856	(58%)	1278	(86%)

PHARMACOLOGY

Gentamicin Serum Levels via the Intramuscular Route in Adults: In patients with normal renal function, peak serum concentrations that are bactericidal for susceptible bacteria occur between 30 and 90 minutes after injection, the peak serum level (mcg/mL) being four times the single dose (mg/kg). The mean serum half-life is approximately two hours.

Gentamicin Serum Levels via the Intramuscular Route in Infants and Neonates: Peak serum concentrations of 2.2 mcg/mL to 8.6 mcg/mL (mean 4.0 mcg/mL) are observed one-half to one hour after 2.5 mg/kg of gentamicin are administered intramuscularly, injection to infants 7 days of age and under.

The mean serum gentamicin half-life is approximately five hours in neonates under 72 hours of age. The half-life may be considerably prolonged in infants weighing less than 1500 grams (3.3 lb). In low-birth-weight infants, prolonged half-life values may extend through the second week of life. In contrast, values of 3 to 3 1/2 hours are usually observed in full-term infants who are 7 days of age or older.

Concentrations of gentamicin in serum of infants 2 to 24 months of age following IM doses of 2.0 and 2.5 mg/kg were shown to be in the range of 2.5 to 7.5 mcg/mL.

Gentamicin Serum Levels via the Intravenous Route in Adults: After a two-hour infusion of a dose of 1 mg/kg to a group of patients, peak gentamicin concentrations were reached at the end of the infusion and averaged 4.5 mcg/mL (range 0.5 to 8 mcg/mL).

Slow intravenous injection at recommended doses gave serum levels of 5 to 9 mcg/mL after 10 minutes.

The mean serum half-life is the same as for the intramuscular route of administration.

Gentamicin Serum Levels via the Intravenous Route in Infants and Neonates: Levels in serum and half-life values after intravenous infusion of gentamicin were similar to those after intramuscular administration.

Gentamicin Excretion: In man, about 25-30% of the administered dose of gentamicin is bound by serum protein, it is released as the drug is excreted. Gentamicin is excreted principally in the urine in an unchanged form by glomerular filtration thus resulting in high urinary concentration of the antibiotic. After initial administration to patients with normal renal function, 30-100% of the gentamicin is recoverable in the urine in 24 hours. Renal clearance of gentamicin is similar to that of endogenous creatinine.

In patients with impaired renal function, the clearance of gentamicin is decreased; the more severe the impairment the slower the clearance.

In the newborn, approximately 30% of the administered dose is excreted in 12 hours.

Gentamicin Penetration: Following parenteral administration, gentamicin is detected in tissues and body fluids. Concentration in the bile in general have been low, suggesting minimal biliary excretion. Gentamicin has been found in the cerebrospinal fluid after intramuscular injection; however, concentrations have been low and may be inadequate for treatment of certain central nervous system infections.

Concentrations of gentamicin in the CSF of infants with purulent meningitis range from 0.2-3.5 mcg/mL after a dose of 1.5 to 2.5 mg/kg. Peak values are found four to six hours after the dose, and are dependent on degree of meningeal inflammation and dosage.

Gentamicin has also been found in the sputum, pleural fluid and peritoneal cavity. Gentamicin crosses the peritoneal as well as placental membranes.

Gentamicin, at considerably higher doses than normally recommended, like other aminoglycosides antibiotics, causes neuromuscular blockade in animals. This phenomenon is antagonized by neostigmine or calcium (see **PRECAUTIONS**).

TOXICOLOGY

Gentamicin has been shown to affect vestibular and renal functions in animals and man. Chronic administration of 5 mg/kg for 50 days in dogs, 10 mg/kg for 40 days in cats and 20 mg/kg for 24 days in rats resulted in mild toxicity in some animals studies. Higher toxic doses resulted in damage to renal and vestibular function which appeared to be dose related. In humans, the only serious side effect to date has been damage to the eighth cranial nerve, predominantly the vestibular branch. Proteinuria, and a rise in blood urea nitrogen or serum creatinine have also occurred (see **ADVERSE REACTIONS**). These findings have usually reverted to normal when the drug was discontinued.

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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

GENTAMICIN INJECTION USP
Gentamicin Sulphate

Read this carefully before you start taking **Gentamicin Injection USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Gentamicin Injection USP**.

What is Gentamicin Injection USP used for?

Gentamicin Injection USP is used to treat serious bacterial infections such as:

- blood infections
- chest infections
- infections of system that carries urine out of the body (Urinary tract)
- Bone and tissue infections
- Infected wounds or burns

Antibacterial drugs like **Gentamicin Injection USP** treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, **Gentamicin Injection USP** should be used exactly as directed. Misuse or overuse of **Gentamicin Injection USP** could lead to the growth of bacteria that will not be killed by **Gentamicin Injection USP** (resistance). This means that **Gentamicin Injection USP** may not work for you in the future.

How does Gentamicin Injection USP work?

Gentamicin Injection USP is in a class of medications called aminoglycoside antibiotics. It works by preventing bacteria from growing and by killing them.

What are the ingredients in Gentamicin Injection USP?

Gentamicin Injection USP 10 mg per mL and 40 mg per mL contain:

Medicinal ingredient: Gentamicin as gentamicin sulphate.

Non-medicinal ingredients: disodium edetate dihydrate, sodium bisulfite, sulfuric acid, sodium hydroxide, and water for injection. Gentamicin Injection USP 40 mg per mL also contains: methylparaben and propylparaben

Gentamicin Injection USP comes in the following dosage forms:

Gentamicin Injection USP comes a sterile solution (liquid) containing 10 mg per mL or 40 mg per mL of gentamicin as gentamicin sulphate.

Do not use Gentamicin Injection USP if you have an allergy to:

- to gentamicin
- other aminoglycosides antibiotics such as amikacin, kanamycin, parmomycin, streptomycin, tobramycin
- any of the other ingredients in **Gentamicin Injection USP** (see What are the ingredients in Gentamicin Injection USP?)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Gentamicin Injection USP. Talk about any health conditions or problems

you may have, including if you:

- have a history of kidney problems and/or diabetes
- have a history of hearing problems or if you have been treated with medicines that affect hearing in the past (see “The following may interact with **Gentamicin Injection USP**” section)
- have problems with balance
- have a history of muscles problems such as myasthenia gravis or Parkinson’s disease.
- are pregnant or planning to become pregnant
- are breastfeeding or planning to breastfeed

Other warnings you should know about:

Gentamicin Injection USP may harm your hearing or your kidneys (see “**Serious Side Effects and What to do About Them**” section). While you are using **Gentamicin Injection USP**, your healthcare professional may do bloodwork to check how your kidneys are working. Sometimes you may also take a hearing test to check if **Gentamicin Injection USP** is not affecting your hearing.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Gentamicin Injection USP:

- Medications that affect your kidneys or hearing such as:
 - Other antibiotics;
 - aminoglycosides (e.g. amikacin, kanamycin, parmomycin, streptomycin tobramycin)
 - cephalosporins such as cefazolin, cefixime or cephalexin
 - clindamycin
 - carbenicillin, piperacillin, polymixin B, colistin
 - vancomycin
 - Amphotericin B, a medicine used to treat fungal infections
 - Anti-cancer drugs, such as cisplatin and carboplatin
 - Diuretics, “water pills” such as ethacrynic acid or furosemide
 - Medicines used to suppress the immune system, such as cyclosporine and tacrolimus
 - Medications used to reduce fever and inflammation (nonsteroidal anti-inflammatory) such as indomethacin
 - Zalcitabine, an HIV medication
 - Mannitol
- Medications given during surgery to relax the muscles such as tubocurarine and succinylcholine
- Medicines used to treat myasthenia gravis such as neostigmine and pyridostigmine.
- Magnesium

Many other medications may also interact with gentamicin. Tell your healthcare professional about all the medications you are taking, even those that do not appear on this list.

How to take Gentamicin Injection USP:

Your healthcare professional will give **Gentamicin Injection USP** as a shot into a muscle or as a slow drip through a needle into a large vein (infusion).

Usual dose:

Your healthcare professional will decide on the dose that is right for you. This will depend on your age, weight, type of infection and how well your kidneys are working.

Your healthcare professional will also tell you how long to use **Gentamicin Injection USP**

Ask your healthcare professional if you have any questions about how many doses of **Gentamicin Injection USP** you will need or when you will receive them.

Overdose:

If you think you have been given too much **Gentamicin Injection USP**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Gentamicin Injection USP is administered by a healthcare professional. If you think you have missed a dose talk to your healthcare professional.

What are possible side effects from using Gentamicin Injection USP?

These are not all the possible side effects you may feel when taking **Gentamicin Injection USP**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- nausea, vomiting
- decreased appetite
- weight loss
- weakness or tiredness
- increased salivation
- rash (area of itchy, red, irritated or swollen skin)
- hives (red and sometimes itchy bumps on your skin)
- headache
- pain at injection site
- joint pain
- fever

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Kidney Problems: dark-coloured urine, increased/decreased urination, unusual tiredness or weakness, nausea, vomiting, swelling of the arms or legs			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hearing Problems: dizziness, hearing loss, ringing in the ears, problems with balance, sensation of spinning			✓
UNKNOWN FREQUENCY Nervous System Problems: trouble walking, dizziness, numbness, skin tingling, muscle twitching, seizure (fits), trouble breathing			✓
Serious Allergic Reaction (hypersensitivity): swelling of the face, lips, tongue or throat, trouble breathing or swallowing, itching, hives, skin rash with or without blisters or peeling			✓
Decreased of cells in the blood that help the blood clot (Platelets): •easy bruising, •abnormal bleeding, bleeding when you brush your teeth, •Pinpoint red spots on the skin		✓	
Decreased White Blood Cells: (usually found when your doctor orders tests) more likely to develop infections, fatigue, fever, aches, pains and flu-like symptoms		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Gentamicin Injection USP vials should be protected from light and stored at room temperature (15 – 30 °C).

Keep out of reach and sight of children.

If you want more information about Gentamicin Injection USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.sandoz.ca, or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

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