GENTAMICIN
INJECTION, USP
(PEDIATRIC)

20 mg/2 mL

Gentamicin sulfate equivalent to 10 mg/mL; Water for Injection q.s. Sodium hydroxide and/or sulfuric acid may have been added for pH adjustment.

Usual Dosage: See insert.

Warning: Patients treated with gentamicin and other aminoglycosides should be under close clinical observation because of the potential toxicity. See Warnings and Precautions in the insert.

Store at 20° to 25°C [see USP Controlled Room Temperature]. This container closure is not made with natural rubber latex.
GENTAMICIN INJECTION, USP

40 mg/mL Gentamicin equivalent
For IM or IV Use
Must be diluted for IV use

2 mL Multiple Dose Vial
Sterile Rx only
80 mg/2 mL

Lake Zurich, IL 60047
Fresenius Kabi USA, LLC
25 Vials

BLACK 431C

CrossTech—72324—Proof A2
Form M01
Fresenius Kabi USA, LLC
P.O. 4500121296—Job No. 42625F
8/14/13—hc—R—Indd4

Reference ID: 3466754
Sterile
Each mL contains: Gentamicin sulfate equivalent to 40 mg/gentamicin; 1.8 mg methylparaben and 0.2 mg propylparaben as preservatives; 3.2 mg sodium metabisulfite; 0.1 mg disodium edetate; Water for Injection q.s. Sodium hydroxide and/or sulfuric acid may have been added for pH adjustment.

Usual Dosage: See insert.

Warning: Patients treated with gentamicin sulfate and other aminoglycosides should be under close observation because of the potential toxicity. See Warnings and Precautions in the insert.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This container closure is not made with natural rubber latex.

NDC 63323-010-20  1020
GENTAMICIN INJECTION, USP
800 mg/20 mL
40 mg/mL
Gentamicin equivalent
For IM or IV Use. Must be diluted for IV use.
20 mL Multiple Dose Vial

Fresenius Kabi USA, LLC
Lake Zurich, IL 60047

Reference ID: 3466754
Each mL contains: Gentamicin sulfate equivalent to 40 mg gentamicin; 1.8 mg methylparaben and 0.2 mg propylparaben as preservatives; 3.2 mg sodium metabisulfite; 0.1 mg disodium edetate; Water for Injection q.s. Sodium hydroxide and/or sulfuric acid may have been added for pH adjustment.

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Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

This container closure is not made with natural rubber latex.
GENTAMICIN INJECTION, USP

DESCRIPTION: Gentamicin sulfate, a water-soluble antibiotic of the aminoglycoside group, is the free base of gentamicin hydrochloride. Gentamicin, an aminoglycoside, is a bactericidal antibiotic of the neomycin family to which it is chemically related. It is used in the treatment of serious infections caused by susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. The availability of aminoglycosides for parenteral use provides a useful supplement to the range of potentially useful therapeutics in the treatment of clinically severe infections in which the causative organisms are considered to be susceptible to the aminoglycosides.

CLINICAL PHARMACOLOGY: After intramuscular or intravenous administration of gentamicin sulfate, peak serum concentrations are reached between 30 and 60 minutes and serum levels are maintained for 6 to 8 hours. The absorption of gentamicin from the gastrointestinal tract is variable. In the absence of diarrhea, there is an extensive first-pass effect on oral administration resulting in a bioavailability of less than 10%. Approximately 80% of a single intramuscular or intravenous dose of gentamicin is absorbed systemically. The distribution of gentamicin is variable and is affected by the concentration of protein and the presence of cells or the material administered. Gentamicin is 90% to 95% bound to plasma proteins. Approximately 70% of a single intramuscular or intravenous dose is excreted in the urine within 24 hours as unchanged gentamicin. The amount of gentamicin in the urine is directly related to the effectiveness of renal function. In patients with renal insufficiency, gentamicin is distributed more widely and the drug is excreted more slowly. When renal function is not maintained or is significantly decreased, the systemic availability of gentamicin is increased. Gentamicin is slowly redistributed and the plasma level of the drug may be maintained post injection until after completion of the treatment course. Gentamicin is primarily eliminated from the body by glomerular filtration and active tubular secretion. Gentamicin metabolites are not found in the urine. Gentamicin is not metabolized to any significant extent in the body.

Indications: Gentamicin is indicated in the treatment of serious infections caused by susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphylococcus aureus. Gentamicin is also indicated in the treatment of infections due to susceptible strains of the following microorganisms: aerobic gram-negative bacilli, Pseudomonas aeruginosa, Proteus mirabilis, Escherichia coli, Klebsiella pneumoniae, Enterobacter aerogenes, and Staphyloco...
Becomes compromised professional report of pain at the injection site. Subcutaneous, hypocalcemia and hypokalemia.

Gentamicin; anemia, leukopenia, granulocytopenia, dermatologic syndrome, pulmonary fibrosis, alopecia, joint pain, generalized burning, laryngeal edema, anaphylactoid reactions, risk of immediate, irreversible.

The rate of removal of casts, cells or protein in the urine or oliguria, presence of casts, cells or protein in the urine or oliguria, concentration is recommended as a basis for dosage adjustment. When Gentamicin Injection, USP is prescribed to treatable by Gentamicin Injection, USP or other bacteria will develop resistance and will not be completed the full course of therapy may not completing the full course of therapy may be less. The solution may be infused over a period of one-half to two hours.

When Gentamicin Injection, USP is prescribed to patients with high doses and/or prolonged therapy due to rising BUN, NPN, serum creatinine or oliguria, not completing the full course of therapy may not completing the full course of therapy may be less. The solution may be infused over a period of one-half to two hours.

Serious adverse effects on both vestibular and auditory function of the inner ear have been reported for patients with high doses and/or prolonged therapy as a result of rising BUN, NPN, serum creatinine or oliguria, not completing the full course of therapy may not completing the full course of therapy may be less. The solution may be infused over a period of one-half to two hours.

Relevant laboratories are involved in the evaluation of creatinine clearance and the status of the patient's host-defense mechanisms. A rough guide for determining reduced dosage at the beginning of therapy, incorrect to recognize that deterioration in renal function may occur, especially in patients with stable renal impairment.

Serious adverse effects on both vestibular and auditory function of the inner ear have been reported for patients with high doses and/or prolonged therapy. Therefore, it is desirable to measure both peak and trough serum concentrations is recommended as a basis for dosage adjustment.

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**GENTAMICIN INJECTION, USP (Pediatric)**

**DESCRIPTION**
Gentamicin sulfate, a water-soluble antibiotic of the aminoglycoside group, is an antibiotic. It is a semisynthetic product derived from the actinomycete, *Streptomyces gentianus*. The parenteral form is a sterile, lyophilized, white or nearly white, odorless powder. It is available in single-dose packages for subcutaneous, intramuscular, and intravenous injection in quantities of 50 mg and 100 mg.

### CLINICAL PHARMACOLOGY:

#### Aminoglycosides

Gentamicin is an aminoglycoside antibiotic that is active against aerobic and some anaerobic Gram-negative bacteria. It is bactericidal in vitro against a wide variety of Gram-negative organisms, including strains of *Pseudomonas aeruginosa*. Gentamicin has been shown to be active against *Prevotella* and *Bacteroides* species.

### INDICATIONS AND USAGE:

- **Intravenous** Injection for use in the following indications: congenital or acquired infections caused by susceptible strains of the following organisms:
  - *Pseudomonas aeruginosa*;
  - *Streptococcus pyogenes*;
  - *Staphylococcus aureus*;
  - *Escherichia coli*;
  - *Citrobacter freundii*.

### CONTRAINDICATIONS:

- Hypersensitivity to any aminoglycoside antibiotic.
- Patients with dehydration, congestive heart failure, or arteriosclerotic cardiovascular disease.

### WARNINGS:

- **Neurotoxicity and Otoxicity**: Gentamicin should be used with caution in patients with impaired renal function or high doses or prolonged treatment. Gentamicin has been shown to cause irreversible hearing loss and loss of renal function. Gentamicin toxicity can occur with all aminoglycosides and can be caused by toxicity to the renal tubular epithelium and the renal cortex.

### PRECAUTIONS:

- **Drug Interactions**: Gentamicin should be used with caution in combination with other nephrotoxic or ototoxic drugs, such as cephalosporins or polymyxin B.

### DOSAGE AND ADMINISTRATION:

- **Dosage**:
  - **Adults**: 1 to 2 mg/kg per hour for 1 to 5 hours, followed by 1 mg/kg per hour for 1 to 4 hours.
  - **Children**: 1 to 2 mg/kg per hour for 1 to 5 hours, followed by 1 mg/kg per hour for 1 to 4 hours.

- **Monitoring**:
  - **Blood trough levels**: Monitor blood trough levels every 12 hours to ensure the patient is not receiving serum gentamicin levels that are too high.
  - **Urinary drug levels**: Monitor urinary drug levels every 6 hours to ensure the patient is not receiving serum gentamicin levels that are too low.

### ADVERSE REACTIONS:

#### Hematologic

- **Anemia**, **thrombocytopenia**

#### Nervous System

- **Neurotoxicity**

#### Other

- **Postural hypotension**

### DOSAGE FORMS:

- **Powder for Injection**
- **Solution for Injection**

### PATIENT INFORMATION:

- **Cautions**:
  - **Hypersensitivity**
  - **Renal Failure**

###编制
Gentamicin Injection, USP (Preservative Free) is a sterile, single-use, ready-to-use solution of gentamicin sulfate for injection.

**WARNINGS**

1. Do not administer unless solution is clear and colorless.
2. Discard if there is evidence of bacterial contamination or if solution has changed color or appearance.
3. Store at 27°C (80°F) to 77°F (25°C) unless otherwise specified.

**REFERENCES**