**Vancomycin Hydrochloride for Injection, USP**

**Rx only**

The development of resistance to vancomycin results in the ineffective treatment of infections caused by Staphylococcus aureus (SA), other enterococci, and some streptococci.

**DESCRIPTION**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is a white or almost white, odorless powder for injection. The vancomycin content of each of the 10 g and 50 g Pharmacy Bulk Package bottles is 10 g and 50 g, respectively, equivalent to 10 g and 50 g of vancomycin hydrochloride. The pH of the solution is between 2.5 to 4.5. Vancomycin is a highly active, water-soluble antibiotic produced by the actinomycete **Streptomyces orientalis** in nature. Vancomycin is a peptidoglycan synthesis inhibitor that interferes with the biosynthesis of the bacterial cell wall. The active principle is vancomycin hydrochloride.

**INDICATIONS AND USAGE**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is indicated for the treatment of infections caused by **Staphylococcus aureus** (SA), other enterococci, and some streptococci.

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is not effective by the oral route for other types of infections.

**CONTRAINDICATIONS**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is contraindicated in patients who have previously experienced a reaction to vancomycin or to any other member of the streptoglycosides. The syndromes associated with these reactions have included anaphylactic and anaphylactoid reactions, exfoliative dermatitis, toxic epidermal necrolysis, Stevens-Johnson syndrome, and renal failure.

**WARNINGS**

**Rapid Intravenous Administration**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** should be administered by slow intravenous injection. If the rate of administration is increased to approximately 150 mg per minute, the frequency and severity of infusion-related reactions increase.

**Infusion Reactions**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** should be administered slowly as a dilute solution (2.5 to 5 g/L) and by rotation of venous access sites.

**Pain, Tenderness, and Necrosis**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** should be used with aseptic technique, and the administration set used should be changed by the end of each 24-hour period. The use of large-bore needles or catheters is not recommended.

**DOSAGE AND ADMINISTRATION**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is administered by slow intravenous injection. The solution should be free of particulate matter.

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible organisms, and should only be used to treat infections for which there is no effective alternative therapy.

**PREGNANCY AND NURSING MOTHERS**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is not known to have adverse effects on reproduction in animals or adverse effects on fetal development in animals. It is unknown whether **VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** can cause fetal harm when administered to pregnant women. Use in pregnancy should only be considered when the potential benefit justifies the potential risk to the fetus.

**ADVERSE REACTIONS**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is generally well tolerated. Although the frequency of infusion-related reactions decreases with repeated doses, these reactions may recur. In some instances, infusion-related reactions occur that are unusual and unpredictable.

**Laboratory Test Interference**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** may interfere with the results of certain laboratory tests. When available, the clinical microbiology laboratory should provide the results of such laboratory tests.

**ADVERSE REACTIONS**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** may cause the following adverse reactions:

- **Allergic reactions:** Because of the frequent use of vancomycin, increased sensitivity reactions have been reported.
- **Hypersensitivity:** Severe anaphylactoid reactions, usually occurring within 30 minutes, but sometimes as late as 24 hours, have been reported. Transitory decreases in blood pressure have been reported with anaphylactoid reactions.
- **Nephrotoxicity:** Nephrotoxicity has been reported in patients with renal dysfunction or treated with vancomycin for extended periods of time.
- **Renal Failure:** Renal failure has been reported in patients receiving vancomycin for extended periods of time.
- **Hypersensitivity:** Hypersensitivity reactions have been reported in patients receiving vancomycin for extended periods of time.
- **Fibrin Deposition:** Fibrin deposition has been reported in patients receiving vancomycin for extended periods of time.
- **Pseudomembranous Colitis:** Pseudomembranous colitis has been reported in patients receiving vancomycin for extended periods of time.
- **Bone Marrow Suppression:** Bone marrow suppression has been reported in patients receiving vancomycin for extended periods of time.
- **Hematological Changes:** Anemia, leukopenia, leukocytosis, and eosinophilia have been reported in patients receiving vancomycin for extended periods of time.
- **Gastrointestinal Changes:** Gastrointestinal changes, including diarrhea, have been reported in patients receiving vancomycin for extended periods of time.
- **Hepatic Changes:** Hepatic changes, including jaundice, have been reported in patients receiving vancomycin for extended periods of time.
- **Skin Reactions:** Skin reactions, including urticaria, have been reported in patients receiving vancomycin for extended periods of time.
- **Necrotizing Fasciitis:** Necrotizing fasciitis has been reported in patients receiving vancomycin for extended periods of time.
- **Necrotizing Spondylitis:** Necrotizing spondylitis has been reported in patients receiving vancomycin for extended periods of time.
- **Necrotizing Enterocolitis:** Necrotizing enterocolitis has been reported in patients receiving vancomycin for extended periods of time.
- **Neurotoxicity:** Neurotoxicity has been reported in patients receiving vancomycin for extended periods of time.
- **Bone Marrow Suppression:** Bone marrow suppression has been reported in patients receiving vancomycin for extended periods of time.
- **Thrombophlebitis:** Thrombophlebitis has been reported in patients receiving vancomycin for extended periods of time.
- **Arthritis:** Arthritis has been reported in patients receiving vancomycin for extended periods of time.
- **Other Reactions:** Other reactions have been reported in patients receiving vancomycin for extended periods of time.

**OVERDOSAGE AND TOXICITY**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is not known to have any curative or therapeutic potential for overdosage situations.

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**CONTRAINDICATIONS**

**VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP** is not effective by the oral route for other types of infections.
Vancomycin Dose mg/24 hr

| 1,545 | 1,390 | 310 | 925 | 620 | 1,235 |

The usual daily intravenous dose is 2 g divided either as 500 mg every six hours or 1 g every 12 hours.

Concentrations of no more than 5 mg/mL and rates of no more than 10 mg/min are recommended.

In managing overdosage, consider the possibility of multiple drug interactions.

Physicians’ Desk Reference (PDR). In managing overdosage, consider the possibility of multiple drug interactions.

Onset of pseudomembranous colitis symptoms may occur during or after antibiotic treatment (see Gastrointestinal).

Gastrointestinal

Inflammation at the injection site has been reported.

Phlebitis

In rare instances, patients have been reported to have had anaphylaxis, drug fever, nausea, chills, eosinophilia, rash, and hypotension (see WARNINGS).

ANIMAL PHARMACOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal reproduction studies have not been conducted with vancomycin. It is not known whether vancomycin can cause fetal harm when administered to a pregnant woman or can cause decreased fertility in males or females. Vancomycin should be given to pregnant women only if clearly needed.

Pregnancy

Vancomycin is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman. Because of the potential for serious adverse reactions in nursing infants following the administration of vancomycin, a decision should be reaches whether nursing should be discontinued or whether the drug benefits outweigh the potential for adverse reactions in the nursing infant.

Nursing Mothers

Vancomycin solution has a low pH and may cause physical instability of other compounds.

In compatible combinations, vancomycin may be added to sterile water for injection, USP, dextrose-containing solutions, or electrolyte solutions. Other solutions may not be suitable. The pH of the final solution should be measured to ensure that the final solution is not alkaline (pH > 7.5) or acidic (pH < 4.5).

- Normosol® 5% Dextrose and Lactated Ringer’s Injection
- Normosol® 5% Dextrose Injection, USP
- D5W (D5W = 5% Dextrose in Water for Injection)
- 5% Dextrose Injection, USP
- 5% Dextrose Injection, USP
- 10% Dextrose Injection, USP
- 10% Dextrose Injection, USP
- 20% Dextrose Injection, USP
- 100% Dextrose Injection, USP
- 10% Sodium Chloride Injection, USP
- 20% Sodium Chloride Injection, USP
- 10% Lactated Ringer’s Injection
- 0.9% Sodium Chloride Injection
- 0.9% Sodium Chloride Injection

The serum creatinine must represent a steady state of renal function. Otherwise, the estimated value based on the creatinine clearance is only an estimate.

The following tables on dosage adjustment are based on the patient’s actual creatinine clearance.

The table is not valid for functionally anephric patients. For such patients, an initial dose of 15 mg/kg of body weight should be given prior to therapeutic vancomycin dosing. The dosage of vancomycin per day in mg is about 1.9 times the glomerular filtration rate in mL/min (see following table). The dosage of vancomycin per day in mg is about 1.9 times the glomerular filtration rate in mL/min (see following table).

For Oral Administration

Dosage adjustment must be made in patients with impaired renal function. In premature infants and in elderly, dosage reduction must be made for multiple drug interactions.

REFERENCES

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- 10% Dextrose Injection, USP
- 20% Dextrose Injection, USP
- 100% Dextrose Injection, USP
- 10% Sodium Chloride Injection, USP
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