Vancomycin dosage schedules should be adjusted in elderly patients (see Table 1). The following formula (based on sex, weight, and age of the patient) may be used to estimate the dosage in elderly patients:

\[
\text{Dosage} = \text{Age} \times \text{Weight} \times 0.85 \times 2 \times 0.5
\]

where:
- \(\text{Age}\) is expressed in years
- \(\text{Weight}\) is expressed in kilograms
- The sex factor is 1 for men and 0.75 for women

When only the serum creatinine concentration is known, the following formula (based on sex, weight, and age of the patient) may be used to estimate the dosage in elderly patients:

\[
\text{Dosage} = \frac{\text{Weight}}{2 \times \text{Creatinine} \times 0.85 \times 2 
\]

where:
- \(\text{Weight}\) is expressed in kilograms
- \(\text{Creatinine}\) is the serum creatinine concentration in milligrams per deciliter
- The sex factor is 1 for men and 0.75 for women

When anuria is accompanied by severe heart failure, or oliguria; (2) in which a normal relationship between muscle mass and total body weight is not present, such as obese patients

\[
\text{Dosage} = \frac{\text{Weight} \times 0.85 \times 2 \times 0.5}{\text{Creatinine}}
\]

where:
- \(\text{Weight}\) is expressed in kilograms
- \(\text{Creatinine}\) is the serum creatinine concentration in milligrams per deciliter
- The sex factor is 1 for men and 0.75 for women

In normal volunteers, vancomycin was infused over 60 minutes without any infusion-related events. However, in a study of endophthalmitis due to vancomycin-resistant enterococci, vancomycin was administered by slow infusion over 60 minutes. The precipitates dissolved gradually, with complete resolution of the clinical signs of infection.

The usual intravenous dosage of vancomycin is 10 mg/kg per dose given every six hours. Each dose should be administered over a period of at least one hour. However, in cases of severe infection, such as endocarditis, the dosage may be increased to 25 mg/kg per dose given every six hours. The vials contain sterile vancomycin hydrochloride equivalent to 500 mg, 750 mg, or 1 g vancomycin activity. Vancomycin hydrochloride is a chromatographically purified tricyclic glycopeptide antibiotic derived from Streptomyces orientalis.

In patients with impaired renal function, the dosage of vancomycin should be adjusted based on the estimated creatinine clearance. The following table provides dosages for different levels of creatinine clearance:

<table>
<thead>
<tr>
<th>Estimated Creatinine Clearance (mL/min)</th>
<th>Dosage (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;100</td>
<td>10</td>
</tr>
<tr>
<td>50 – 100</td>
<td>5</td>
</tr>
<tr>
<td>≤50</td>
<td>2.5</td>
</tr>
</tbody>
</table>

If vancomycin is given by a slow infusion over 60 minutes, infusion-related events did not occur in normal volunteers. However, in studies of endophthalmitis due to vancomycin-resistant enterococci, vancomycin was administered by slow infusion over 60 minutes. The precipitates dissolved gradually, with complete resolution of the clinical signs of infection.

In summary, vancomycin is a useful antibiotic for the treatment of serious infections, such as endocarditis and endophthalmitis due to vancomycin-resistant enterococci. However, the dosage should be adjusted based on the estimated creatinine clearance and the severity of the infection.

To report SUSPECTED ADVERSE EVENTS, contact FDA at 1-800-FDA-1088 or 1-800-332-1088.
Vancomycin Hydrochloride for Injection, USP

**Flampy Vial For Intravenous Use**

To use vancomycin hydrochloride, read the entire prescribing information carefully before use. In the event of any ambiguity, consult the manufacturer.

**DESCRIPTION**

Vancomycin hydrochloride for injection, USP consists of vancomycin hydrochloride. The hydrochloride salt is a white to slightly off-white, amorphous, odorless powder with a molecular formula of C₂₃H₂₇ClN₄O₁₄. The vancomycin hydrochloride solution contains approximately 122 mg of sodium per gram of vancomycin hydrochloride. It is available in 1 g and 3 g vials for intravenous injection. The vials contain a filter, which should be removed before use. The sterile solution is isotonic with a pH of approximately 4.0 (2.5 to 4.5). This product is oxygen sensitive.

**INDICATIONS AND USAGE**

Vancomycin hydrochloride is indicated for initial therapy of infections caused by susceptible Gram-positive bacteria, including septicemia, bone infections, lower respiratory tract infections, skin, and skin structure infections. When staphylococci are the suspected pathogen, the resistance of Staphylococcus epidermidis to vancomycin should be considered before therapy is instituted.

**CONTRAINDICATIONS**

Vancomycin hydrochloride is contraindicated in patients with known hypersensitivity to this antibiotic.

**WARNINGS**

Prolonged use of vancomycin may result in the overgrowth of nonsusceptible microorganisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be initiated.

**PRECAUTIONS**

- **C. difficile**
  - Pseudomembranous colitis may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of Clostridium difficile, which carries a high risk of colitis.
  - In rare cases, an overgrowth of Clostridium difficile produces toxins A and B leading to severe colitis with fatal outcome.
  - If Clostridium difficile colitis is suspected, diagnostic tests should be undertaken and appropriate treatment should be instituted.

**ADVERSE REACTIONS**

Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

**INTERACTIONS**

The combination of vancomycin and an aminoglycoside acts synergistically against susceptible Gram-positive bacteria. Antibiotics are used as adjuncts to appropriate surgical measures.

**STORAGE**

Vancomycin hydrochloride is stored at room temperature. After dilution, the solution should be stable for 24 hours at room temperature and should be refrigerated if not used immediately.

**NURSING CONSIDERATIONS**

- **Injection Site:** Vancomycin hydrochloride is irritating to tissue and must be given by a secure intravenous route of administration. Pain, tenderness, and necrosis can occur with intramuscular administration.

**SUPPLEMENTAL INFORMATION**

- **Microdilution:** Vancomycin hydrochloride is susceptible to the microdilution method using a standardized inoculum and concentrations of vancomycin powder. The MIC values should be interpreted according to the criteria in Table 1.

**Microdilution Method**

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Organism (ATTC #)</th>
<th>MIC range (mcg/mL)</th>
<th>Disk diffusion range (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>(29212)</td>
<td>1 – 4</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**DISCLAIMER**

This information is not intended to replace the advice of a healthcare professional. It is provided for general information purposes only. Always consult a healthcare professional before using any medication.
The following item has been administered as a single intravenous infusion at a rate of 13.3 mL/min. In animal studies, hypotension and bradycardia occurred in dogs receiving an intravenous infusion of vancomycin, 25 mg/kg, at a concentration of 25 mg/mL and an infusion rate of 10 mg/min or less. Infusion-related events may occur, however, at any rate or concentration.

**ANIMAL PHARMACOLOGY**

Vancomycin Hydrochloride for Injection, USP is supplied as a sterile powder in single-dose fliptop vials that contain the vancomycin equivalent of either 500 mg or 1 g. Maintenance doses of 250 to 1000 mg once every several days rather than administering the drug on a daily basis. In anuria, a dose of 1000 mg every 7 to 10 days has been given with improvement of visual acuity.

**Compatibility with Other Drugs and Intravenous Fluids**

Reversible neutropenia, usually starting one week or more after onset of therapy with vancomycin or after a total dosage of more than 25 g, has been reported for several dozen patients. Neutropenia appears to be promptly reversible when vancomycin hydrochloride is discontinued. Thrombocytopenia has also been reported. The risk of neutropenia is increased by concomitant treatment with aminoglycosides, anhydrates, and furosemide. Neutropenia has occurred in 0.5% to 2.0% of patients receiving vancomycin and is usually reversible.

**DOSAGE TABLE FOR VANCOMYCIN**

<table>
<thead>
<tr>
<th>Creatinine Clearance</th>
<th>Vancomycin Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>mL/min</td>
<td>mg/24 h</td>
</tr>
<tr>
<td>10</td>
<td>155</td>
</tr>
<tr>
<td>20</td>
<td>310</td>
</tr>
<tr>
<td>40</td>
<td>620</td>
</tr>
<tr>
<td>70</td>
<td>1,080</td>
</tr>
</tbody>
</table>

**OVERDOSAGE**

If creatinine clearance can be measured or estimated accurately, the dosage for most patients with renal impairment can be calculated using the following table. The dosage is based on the following: 1. the minimum renal clearance for satisfactory bacteriostatic serum levels; 2. the maximum renal clearance for which the serum level is reliably pharmacologically insignificant; and 3. the average renal clearance for which there are no reports of toxic effects. The dosage for patients with severe renal impairment can also be determined using the formula for calculating creatinine clearance.

**TERATOGENIC EFFECTS**

It is not known whether vancomycin causes fetal harm. Studies in animals have not been done to evaluate the effects of vancomycin on reproduction. Vancomycin should be given to a pregnant woman only if clearly needed.

**REFERENCES**

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