Vancomycin Hydrochloride for Injection, USP

**HOW SUPPLIED**

Vancomycin Hydrochloride for Injection, USP is supplied as a sterile powder in single-dose ADD-Vantage vials that contain either 500 mg, 750 mg, or 1 g vancomycin hydrochloride and an infusion rate of 13.3 mL/min.

**ADVERSE REACTIONS**

Vancomycin hydrochloride is supplied for injection, intravenous use only. The most common side effects of vancomycin include hyperglycemia, nausea, vomiting, diarrhea, constipation, and pruritus.

**PRECAUTIONS**

Vancomycin hydrochloride is not effective by the oral route for other types of infection. Use of vancomycin hydrochloride is contraindicated in patients with a history of anaphylactic reactions to vancomycin or to any of its components.

**DOSAGE AND ADMINISTRATION**

Vancomycin dosage schedules should be adjusted in elderly patients (see Table 2).

**SPECIFIC DOSAGE INFORMATION**

**Adolescents**

The daily maintenance dosage of vancomycin should not exceed 15 mg/kg/day. When the glomerular filtration rate is less than 10 mL/min, vancomycin dose should be adjusted according to the following table.

<table>
<thead>
<tr>
<th>Serum Creatinine Concentration (mg/dL)</th>
<th>Dose of Vancomycin (mg/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>25-50 mg/dL</td>
</tr>
<tr>
<td>3-6</td>
<td>50-75 mg/dL</td>
</tr>
<tr>
<td>6-9</td>
<td>75-100 mg/dL</td>
</tr>
<tr>
<td>≥9</td>
<td>100-125 mg/dL</td>
</tr>
</tbody>
</table>

**ADDITIONAL INFORMATION**

**Use of microbiologic assay, radioimmunoassay, fluorescence polarization immunoassay, fluorescence immunoassay, or high-pressure liquid chromatography for vancomycin dose determination is discouraged.**

**Quality Control**

The following quality control strains are recommended for vancomycin susceptibility testing:

- Staphylococcus aureus (29213)
- Streptococcus agalactiae
- Streptococcus pyogenes
- Streptococcus pneumoniae
- Enterococcus faecalis
- Enterococcus faecium
- Enterococcus hirae
- Lactobacillus plantarum
- Lactobacillus rhamnosus

**REFERENCES**


**NOTICE**

Vancomycin hydrochloride is supplied for injection, intravenous use only. Use of vancomycin hydrochloride is contraindicated in patients with a history of anaphylactic reactions to vancomycin or to any of its components.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JACQUELINE D COUNCIL  
06/12/2012

LILLIE D GOLSON  
06/12/2012  
for Wm. Peter Rickman