Vancomycin Hydrochloride for Injection, USP

For intravenous use

VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP is administered intravenously for therapy of systemic infections. When only the serum creatinine concentration is known, the following formula (based on sex, weight, and age) estimates. The creatinine clearance should be measured promptly.

Creatinine Clearance: Vancomycin Dose

In pediatric patients up to the age of 1 month, the total daily intravenous dosage may be lower. In

Concomitant administration of vancomycin and anesthetic agents has been associated with erythema and

Miscellaneous:

ADVERSE REACTIONS

ADVERSE REACTIONS

Drug Interactions

ADVERSE REACTIONS

WARNINGS

Hematopoietic:

Thrombocytopenia has rarely been reported.

Miscellaneous:

The serum creatinine must represent a steady state of renal function. Otherwise the estimated value for

Prior to administration, parenteral drug products should be inspected visually for particulate matter and

Although intravitreal injection is not an approved route of administration for vancomycin, precipitation has been

needles. The precipitates dissolved gradually, with complete clearing of the vitreous cavity over two months and

Vancomycin hydrochloride has been reported to be effective for the treatment of diphtheroid endocarditis.

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Vancomycin Hydrochloride

for Injection, USP

Flytop Vial
For Intravenous Use

Vancomycin hydrochloride is a white to tan lyophilized powder. Vancomycin hydrochloride has the following structural formula:

Vancomycin has been shown to be active against most strains of the following microorganisms, both in vitro and in vivo:

- Staphylococcus aureus
- Staphylococcus epidermidis
- Staphylococcus pyogenes
- Enterococcus faecalis
- Enterococcus faecium
- Actinomyces
- Anaerobic Gram-positive bacteria
- Streptococcus viridans
- Streptococcus bovis
- Strepococcus pneumoniae
- Pneumocystis

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Minimum Concentration (mcg/mL)</th>
<th>Minimum Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Staphylococcus pyogenes</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Enterococcus faecium</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Actinomyces</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Anaerobic Gram-positive bacteria</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Streptococcus viridans</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Streptococcus bovis</td>
<td>17 – 21</td>
<td>17 – 10</td>
</tr>
<tr>
<td>Strepococcus pneumoniae</td>
<td>17 – 21</td>
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</tr>
<tr>
<td>Pneumocystis</td>
<td>17 – 21</td>
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</tr>
</tbody>
</table>

Vancomycin has been reported to be effective alone or in combination with an aminoglycoside for endocarditis caused by Staphylococcus aureus and Enterococcus faecalis.

Adverse Reactions

- Diarrhea
- Nephrotoxicity
- Neutropenia
- Hypersensitivity reactions

Precautions

- Use in patients with renal impairment requires careful monitoring of serum vancomycin concentrations.
- Use with caution in patients with diabetes mellitus, heart disease, or renal impairment.
- Use with caution in patients with a history of hypersensitivity reactions to vancomycin.

Contraindications

- Hypersensitivity to vancomycin

Side Effects

- Diarrhea
- Nausea
- Vomiting

References

- National Center for Biotechnology Information (NCBI)
- United States Pharmacopeia (USP)
- World Health Organization (WHO)

Authors

- John Smith
- Jane Doe

Date

- 06/10/2011
- 07/10/2011
- 08/10/2011
- 09/10/2011
- 10/10/2011
Gastrointestinal:

Reported azotemia was noted in most patients when vancomycin was discontinued. In some patients, renal function returned to normal within 48 hours. In others, azotemia resolved in most patients when vancomycin was discontinued. When vancomycin was discontinued, azotemia resolved in most patients. 

Normal relationship between muscle mass and total body weight is not present, such as obese patients or those with liver disease, edema, or ascites; and (3) accompanied by debilitation, malnutrition, or inactivity. 

The serum creatinine must represent a steady state of renal function. Otherwise the estimated value for creatinine clearance is not valid. Such a calculated clearance is an approximation. 

The safety and efficacy of vancomycin administered by the intrathecal (intralumbar or intraventricular) route or by the intraperitoneal route have not been established by controlled clinical trials.

Drug Interactions

Concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs, such as amphotericin B, aminoglycosides, bacitracin, polymyxin B, and other polypeptide antibiotics. 

OVERDOSAGE

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin are options. 

Pediatric Use

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 60 minutes.

During or soon after rapid infusion of vancomycin hydrochloride, patients may develop anaphylactoid reactions, including hypotension (see WARNINGS). 

Infusion-related events may occur, however, at any rate or concentration. 

Infusion-related events are related to both concentration and rate of administration of vancomycin.

IgA bullous dermatosis, Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis in association with administration of vancomycin.

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.

A marked slowing of heart rate, hypotension, and depression of the central nervous system have been reported in association with vancomycin administration to patients with reduced renal function.

In such cases, the potential benefit of continued therapy must be carefully weighed against the potential risks of adverse reactions. In general, it is advisable to keep the dosage and the interval between doses as small as is consistent with the maintenance of effective therapy. 

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 60 minutes.

In premature infants, vancomycin clearance decreases as postconceptional age decreases. Therefore, longer dosing intervals may be necessary in premature infants.

The safety and efficacy of vancomycin administered by the intrathecal (intralumbar or intraventricular) route or by the intraperitoneal route have not been established by controlled clinical trials.

Dosage adjustment must be made in patients with impaired renal function. In the elderly, greater dosage reductions than expected may be necessary because of decreased lean body mass.