Information For the Use
Vancomycin (1000mg)

Vancoterm 1000 Injection

Product Information: Vancomycin (1000mg) Injection

Composition:

Each vial contains:

- **Vancomycin: 1000 mg (as Vancomycin Hydrochloride)**

Pharmacological Class:

- **Vancomycin: Glycopeptide antibiotic.**

Indications:

Vancomycin (1000mg) Injection is indicated for the treatment of serious bacterial infections caused by susceptible organisms, including but not limited to:

1. **Infections caused by Gram-positive bacteria:**
    - **Methicillin-resistant Staphylococcus aureus (MRSA).**
    - **Streptococcus pneumoniae (pneumonia, bacteremia).**
    - **Enterococci (endocarditis, urinary tract infections).**
    - **Clostridium difficile-associated diarrhea (CDAD) (oral form is preferred for treatment).**
2. **Serious infections that require intravenous (IV) administration:**
    - **Severe skin and soft tissue infections.**
    - **Bone and joint infections.**
    - **Endocarditis (infection of the heart valves).**
    - **Sepsis.**
    - **Meningitis.**
3. **Prophylaxis:**
    - **Prophylactic use in patients who are undergoing certain surgeries (e.g., cardiac surgery) to prevent infection.**

Mechanism of Action:

Vancomycin is a glycopeptide antibiotic that exerts its bactericidal effect by inhibiting cell wall synthesis in susceptible bacteria. It binds to the D-alanyl-D-alanine portion of the bacterial cell wall precursors, preventing the incorporation of these precursors into the cell wall, thereby weakening the bacterial cell wall and causing bacterial cell death.

Vancomycin is effective against gram-positive bacteria, including resistant strains like MRSA, which makes it a critical drug for treating infections caused by resistant pathogens.

Dosage and Administration:

Dosage:

- **The recommended dosage of Vancomycin (1000mg) depends on the severity of the infection and the patient's weight, renal function, and age. A typical dosing regimen is as follows:**

- **Adult Dose: For most infections, the usual dose is 1g to 2g every 8 to 12 hours, administered intravenously (IV).**
- **For severe infections (e.g., endocarditis, pneumonia), higher doses of 2g every 12 hours may be necessary.**
- **For Clostridium difficile-associated diarrhea (oral form): 125 mg to 500 mg every 6 hours for 10 days.**

Administration:

- **Intravenous Use: Vancomycin should be administered by slow IV infusion (over at least 60 minutes) to prevent adverse reactions such as red man syndrome, which can occur with rapid infusion.**
- **Dilution: The injection should be diluted in 250 to 500 mL of sterile normal saline or 5% dextrose solution. It should not be mixed with other intravenous medications or solutions.**

Monitoring: During treatment, monitor serum vancomycin levels (especially in patients with renal impairment) to ensure therapeutic levels are achieved and to avoid toxicity.

Contraindications:

- **Hypersensitivity to Vancomycin or any of its components.**
- **History of red man syndrome or other severe allergic reactions to Vancomycin.**
- **Renal failure (use with caution and adjust dosing).**

Warnings and Precautions:

- **Nephrotoxicity: Vancomycin can cause kidney damage, especially with high doses or prolonged use. Monitor renal function closely, especially in patients with pre-existing renal disease.**
- **Ototoxicity: Rare cases of hearing loss have been reported, especially with high doses or prolonged therapy. Regular auditory monitoring may be necessary for patients receiving prolonged or high-dose therapy.**
- **Red Man Syndrome: Rapid infusion of Vancomycin can lead to a histamine-mediated reaction, causing flushing, rash, and hypotension. To prevent this, administer the drug slowly over 60 minutes.**
- **Infusion-related reactions: Local reactions (pain, swelling, or redness at the injection site) may occur. Ensure that the drug is infused slowly to minimize these reactions.**
- **Pregnancy and Lactation: Vancomycin should be used during pregnancy only if clearly needed, as it crosses the placenta. It is excreted in breast milk, so caution is required when administering to breastfeeding women.**

Adverse Effects:

- **Common Side Effects:**
  - **Red Man Syndrome (flushing, rash, pruritus).**
  - **Fever, chills, and hypotension during infusion.**
  - **Nausea and vomiting.**
  - **Phlebitis or pain at the injection site.**
- **Serious Side Effects:**
  - **Nephrotoxicity: Signs include decreased urine output, elevated serum creatinine, or proteinuria.**

- **Ototoxicity: Hearing loss or ringing in the ears, especially with high doses or prolonged therapy.**
- **Severe allergic reactions: Anaphylaxis, swelling of the face, tongue, or throat.**
- **Clostridium difficile-associated diarrhea (CDAD): In patients receiving prolonged therapy, or following extended antibiotic courses.**

Drug Interactions:

- **Aminoglycosides (e.g., gentamicin, tobramycin): The combination of Vancomycin with aminoglycosides increases the risk of nephrotoxicity. These drugs should be used cautiously together, and renal function should be monitored closely.**
- **Diuretics (e.g., furosemide): The use of loop diuretics alongside Vancomycin can increase the risk of ototoxicity. Careful monitoring of hearing and renal function is recommended.**
- **Muscle Relaxants (e.g., pancuronium): Vancomycin may enhance the effects of neuromuscular blocking agents, leading to prolonged paralysis.**
- **Other nephrotoxic drugs: Concomitant use with other nephrotoxic agents (e.g., NSAIDs, cyclosporine) should be done cautiously and with monitoring.**

Use in Special Populations:

- **Pregnancy: Vancomycin should be used during pregnancy only if clearly needed, and it should only be administered after considering the potential risks and benefits.**
- **Lactation: Vancomycin is excreted in breast milk, so it should be used with caution in breastfeeding mothers. Only administer if necessary.**
- **Renal Impairment: Dosage adjustments are required for patients with renal dysfunction. Serum vancomycin levels should be monitored to prevent toxicity.**
- **Elderly: The elderly may be more susceptible to nephrotoxicity and ototoxicity. Use the lowest effective dose and monitor renal and hearing functions closely.**

Storage:

- **Store at room temperature (15-30°C).**
- **Protect from light and moisture.**
- **Do not freeze.**
- **Keep out of reach of children.**

Packaging:

- **Available in single-dose vials of 1000 mg Vancomycin.**

Patient Instructions:

1. **Administration: Vancomycin is given intravenously. Ensure you are receiving the correct dose and that the infusion is administered slowly over a period of at least 60 minutes.**
2. **Side Effects: If you experience symptoms like redness, itching, or flushing during the infusion, inform your healthcare provider immediately.**
3. **Renal Monitoring: If you have a history of kidney disease, your doctor may perform regular tests to monitor your kidney function during treatment.**

4. **Hearing: Notify your healthcare provider if you experience hearing loss or ringing in your ears.**
5. **Missed Dose: If you miss a dose, contact your healthcare provider for instructions. Do not administer extra doses to make up for a missed one.**

Vancomycin (1000mg) Injection is an essential antibiotic for treating severe infections caused by gram-positive bacteria, including MRSA. It is a powerful tool for managing infections that do not respond to other antibiotics, especially in hospitalized patients. Always follow the prescribed dosing regimen and seek medical attention for any unusual symptoms or side effects.

Manufactured in India for:

Cafoli Lifecare Pvt. Ltd.
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