Information For the Use
Vancomycin (500mg)

Vancoterm 500 Injection

Product Information: Vancomycin (500mg) Injection

Composition:

Each vial contains:

- **Vancomycin: 500 mg (as Vancomycin Hydrochloride)**

Pharmacological Class:

- **Vancomycin: Glycopeptide antibiotic.**

Indications:

Vancomycin (500mg) Injection is used to treat severe bacterial infections caused by susceptible organisms, including:

1. **Gram-positive Bacterial Infections:**
    - **Methicillin-resistant Staphylococcus aureus (MRSA).**
    - **Streptococcus pneumoniae (e.g., pneumonia, bacteremia).**
    - **Enterococci (e.g., endocarditis, urinary tract infections).**
    - **Clostridium difficile-associated diarrhea (for oral formulation).**
2. **Serious Infections Requiring IV Administration:**
    - **Skin and soft tissue infections (e.g., cellulitis, abscesses).**
    - **Bone and joint infections (e.g., osteomyelitis).**
    - **Endocarditis (heart valve infections).**
    - **Sepsis (bloodstream infections).**
    - **Meningitis (infection of the protective membranes covering the brain and spinal cord).**
3. **Prophylaxis:**
    - **Preoperative prophylaxis in patients at high risk of developing infections, particularly during certain high-risk surgeries (e.g., cardiac surgery).**

Mechanism of Action:

Vancomycin is a glycopeptide antibiotic that works by inhibiting bacterial cell wall synthesis. It binds to the D-alanyl-D-alanine precursor in the bacterial cell wall, preventing the cell wall from being properly built and thereby disrupting the structural integrity of the bacterial cell, leading to bacterial death. Vancomycin is bactericidal against gram-positive organisms, including strains resistant to beta-lactam antibiotics like MRSA.

Dosage and Administration:

Dosage:

- **The recommended dosage of Vancomycin (500mg) depends on the infection severity, patient's renal function, and other individual factors.**
    - **Adult Dose: The typical dose for adults is 500 mg every 6 to 12 hours intravenously (IV), depending on the type and severity**

of the infection. In more severe infections, the dose may be increased to 1g every 8-12 hours.
    - **Pediatric Dose: The usual pediatric dose is 10-15 mg/kg every 6 hours.**
- **For Clostridium difficile-associated diarrhea (oral form): The typical oral dose is 125 mg every 6 hours for 10 days.**

Administration:

- **IV Infusion: Vancomycin should be administered via slow intravenous infusion over 60 minutes to minimize the risk of adverse reactions like red man syndrome (a flushing reaction).**
- **Dilution: Vancomycin should be diluted in a minimum of 100 mL of normal saline or 5% dextrose solution. Ensure that it is properly mixed before administration.**

Renal Adjustment: In patients with impaired renal function, dosing intervals should be adjusted based on the degree of renal insufficiency. Monitoring of serum vancomycin levels is recommended in patients with renal dysfunction to avoid toxicity.

Contraindications:

- **Hypersensitivity to Vancomycin or any of the ingredients in the formulation.**
- **History of severe allergic reactions (e.g., anaphylaxis or red man syndrome) to Vancomycin.**

Warnings and Precautions:

- **Nephrotoxicity: Vancomycin can cause kidney damage, particularly in patients with pre-existing renal impairment or when used with other nephrotoxic agents. Close monitoring of renal function (e.g., serum creatinine and urine output) is essential.**
- **Ototoxicity: High doses or prolonged use of Vancomycin may lead to hearing loss or other auditory disturbances, particularly in patients with impaired renal function. Regular auditory monitoring is recommended for those receiving long-term therapy.**
- **Red Man Syndrome: Rapid intravenous infusion of Vancomycin can cause red man syndrome, a histamine-mediated reaction characterized by flushing, rash, and hypotension. This can be avoided by administering the drug over a period of 60 minutes or more.**
- **Infusion-related reactions: Infusion-related reactions such as pain at the injection site, swelling, or thrombophlebitis may occur. Ensure proper dilution and slow administration to minimize these effects.**
- **Pregnancy and Lactation: Vancomycin is categorized as Pregnancy Category C. It should only be used during pregnancy if absolutely necessary. It is excreted in breast milk, so caution is advised when administering it to breastfeeding mothers.**

Adverse Effects:

- **Common Side Effects:**
    - **Red man syndrome (flushing, rash, pruritus).**
    - **Hypotension during infusion.**
    - **Nausea, vomiting, or gastrointestinal discomfort.**
    - **Pain, swelling, or redness at the injection site.**
- **Serious Side Effects:**
    - **Nephrotoxicity: Signs of kidney damage include decreased urine**

output, elevated serum creatinine, or proteinuria.

- **Ototoxicity: Symptoms of hearing loss or tinnitus (ringing in the ears) may occur, especially at high doses or with prolonged use.**
- **Anaphylaxis: Severe allergic reactions leading to difficulty breathing, swelling of the face, tongue, or throat.**
- **Clostridium difficile-associated diarrhea: Prolonged use of antibiotics like Vancomycin may result in overgrowth of Clostridium difficile, leading to severe diarrhea and colitis.**

Drug Interactions:

- **Aminoglycosides (e.g., gentamicin, tobramycin): The use of Vancomycin with aminoglycosides increases the risk of nephrotoxicity and ototoxicity. If these drugs are co-administered, careful monitoring of kidney function and serum drug levels is necessary.**
- **Loop Diuretics (e.g., furosemide): Co-administration with loop diuretics increases the risk of ototoxicity. Caution is recommended, especially in patients receiving high doses or prolonged therapy.**
- **Muscle Relaxants: Vancomycin may enhance the effects of neuromuscular blockers (e.g., pancuronium), leading to prolonged paralysis. This should be monitored closely.**
- **Other nephrotoxic drugs (e.g., NSAIDs, cyclosporine): Using Vancomycin with other nephrotoxic drugs can increase the risk of kidney damage. Renal function should be closely monitored in such cases.**

Use in Special Populations:

- **Pregnancy: Vancomycin should be used during pregnancy only if clearly needed. It is classified as Category C, meaning that risk to the fetus cannot be ruled out.**
- **Lactation: Vancomycin is excreted into breast milk. It should only be used during breastfeeding if the benefits outweigh the risks.**
- **Renal Impairment: In patients with renal impairment, dosing adjustments are necessary to avoid toxicity. Serum vancomycin levels should be monitored, and drug doses should be adjusted based on kidney function.**
- **Elderly: Elderly patients may be more susceptible to side effects such as nephrotoxicity and ototoxicity. Dosing adjustments and careful monitoring are necessary in older adults.**

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 containing 500 mg of Vancomycin.**

Patient Instructions:

1. **Administration: Vancomycin should be given by a healthcare provider as an intravenous infusion. Ensure that it is administered slowly over 60 minutes to avoid infusion-related reactions.**

2. **Side Effects: If you experience symptoms such as flushing, rash, or dizziness during the infusion, inform your healthcare provider immediately.**
3. **Renal Monitoring: If you have kidney problems, your healthcare provider may monitor your renal function regularly throughout treatment.**
4. **Hearing: Notify your healthcare provider if you experience hearing loss or ringing in the ears.**
5. **Missed Dose: If a dose is missed, contact your healthcare provider for instructions. Do not administer extra doses to make up for a missed dose.**

Vancomycin (500mg) Injection is a vital antibiotic used to treat serious infections caused by resistant gram-positive bacteria, particularly MRSA. It is crucial for managing infections in hospitalized patients. Use under the supervision of a healthcare provider to ensure safe and effective treatment, especially with regard to renal and auditory monitoring during therapy.

Manufactured in India for:

Cafoli™
LIFECARE

Cafoli Lifecare Pvt. Ltd.
(An ISO 9001: 2015 Certified Co.)
Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113