ZERMACIN®

Vancomycin Hydrochloride

Sterile lyophilized powder for solution for I.V. infusion

Zermacin is a white to off-white sterile lyophilized powder which makes a clear solution with a pH range of 2.5 to 4.5 when reconstituted in water.

Composition

1 vial contains sterile vancomycin hydrochloride (USP) equivalent to 0.5 g or 1 g of vancomycin.

Properties

The active ingredient of **Zermacin**, vancomycin, is a purified tricyclic glycopeptide antibiotic derived from *Norcardia orientalis*. It is effective for the treatment of serious or severe infections especially those caused by susceptible strains of methicillin-resistant (beta-lactam resistant) Staphylococci.

Indications

Microbiology: Vancomycin is active against many Gram-positive organisms including Staphylococci, group A beta-hemolytic Streptococci including *Streptococcus pneumoniae,* Enterococci, *Corynebacterium*, and *Clostridium spp.* including *C. difficile.*

Indications: **Zermacin** is effective in the treatment of:

- Infections due to Staphylococci including staphylococcal endocarditis, septicemia, bone infections, lower respiratory tract infections, and skin and skin structure infections.
- Hypersensitive patients, who cannot tolerate or who have failed to respond to other drugs including the penicillins or cephalosporins, and for infections caused by vancomycin susceptible organisms that are resistant to other antimicrobial drugs.

Note: The parenteral form of vancomycin may be administered orally for the treatment of antibiotic-associated pseudomembranous colitis caused by *C. difficile* and for staphylococcal enterocolitis.

Dosage

Adults: The usual daily intravenous dose is 2 g divided either into 0.5 g every 6 hours or 1 g every 12 hours. Each dose should be administered at no more than 10 mg/min or over a period of at least 60 minutes, whichever is longer. Other patient factors, such as age or weight, may call for modification of the usual intravenous daily dose.

Children: The usual intravenous dosage of **Zermacin** is 10 mg/kg given every 6 hours. Each dose should be administered over a period of at least 60 minutes.

Infants and neonates: In neonates and young infants, an initial dose of 15 mg/kg is suggested, followed by 10 mg/kg every 12 hours for neonates in the first week of life and every 8 hours thereafter up to the age of 1 month. Each dose should be administered over 60 minutes. Close monitoring of serum concentrations of vancomycin may be warranted in these patients.

Patients with impaired renal function and elderly patients: Dosage adjustment must be made in patients with impaired renal function. In premature infants and the elderly, greater dosage reductions than expected may be necessary because of decreased renal function. Measurement of vancomycin serum concentrations can be helpful in optimizing therapy, especially in seriously ill patients with changing renal function.

A recommended regimen is as follows:

Creatinine Clearance ml/min	Vancomycin Dose mg/24h
100	1545
90	1390
80	1235
70	1080
60	925
50	770
40	620
30	465
20	310
10	155

The initial dose should not be less than 15 mg/kg, even in patients with mild to moderate renal insufficiency.

The table is not valid for functionally anephric patients. For such patients, an initial dose of 15 mg/kg of body weight should be given to achieve prompt therapeutic serum concentrations. The dose required to maintain stable concentrations is 1.9 mg/kg/24 h. In patients with marked renal impairment, it may be more convenient to give 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 recommended.

If a dose is missed

- Give the missed dose as soon as possible.
- If it is nearly time for your next dose, wait until then to give the medicine and skip the missed dose.
- Do not give two doses at one time.

Reconstitution and administration

Zermacin is administered by slow intravenous infusion for the treatment of systemic infections. The drug is very irritating to tissue and must not be given by intramuscular injection. **Zermacin** is reconstituted by adding 10 or 20 ml of sterile water for injection to a vial labeled as containing 0.5 g or 1 g of vancomycin, respectively, to provide solutions containing 50 mg of the drug per ml. For intermittent I.V. infusion, the reconstituted solutions containing 0.5 g or 1 g must be diluted further with at least 100 ml or at least 200 ml, respectively, of a compatible I.V. solution and administered over a period of at least 1 hour. When intermittent I.V. infusion is not feasible, **Zermacin** may be administered by continuous infusion. In this method, 1-2 g of reconstituted **Zermacin** may be added to a sufficient volume of 0.9% sodium chloride or 5% dextrose injection to permit administration of the desired daily dosage over a 24 hour period. Concentrations of no more than 5 mg/ml and rates of no more than 10 mg/min are recommended in adults. In selected patients in need of fluid restriction, a concentration up to 10 mg/ml may be used. Use of such higher concentrations may increase the risk of infusion-related events that may occur, however, at any rate or concentration.

Note: After reconstitution, solutions retain their potency for 24 hours at room temperature and 96 hours if refrigerated.

Contraindication

Zermacin is contraindicated in patients with known hypersensitivity to vancomycin.

Precautions

Rapid bolus administration (e.g., over several minutes) may be associated with exaggerated hypotension and rarely cardiac arrest. Vancomycin should be administered in a dilute solution over a period of not less than 60 minutes to avoid such complications. Stopping the infusion usually results in prompt cessation of these reactions.

Vancomycin should be used with caution in patients with renal insufficiency because the risk of toxicity is significantly increased by high, prolonged blood concentrations.

Vancomycin should be given to a pregnant woman only if clearly needed. Vancomycin hydrochloride is excreted in human milk. Caution should be exercised when vancomycin is administered to a nursing woman. Because of the potential for adverse events, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Monitoring of vancomycin serum concentrations is recommended in premature neonates and young infants. Elderly patients are more likely to have an age related decrease in renal function, which may require dosage adjustment to avoid excessive vancomycin serum concentrations.

Side effects

Rapid infusion rates of vancomycin have been associated with anaphylactoid reactions including hypotension, wheezing, dyspnea, urticaria, or pruritus. These reactions usually resolve within 20 minutes in most cases.

Nephrotoxicity and ototoxicity have been reported in rare cases, mostly in predisposed patients or those taking concomitantly aminoglycosides or ototoxic drugs, respectively.

Hematopoietic reactions including neutropenia, thrombocytopenia and reversible agranulocytosis have been rarely reported.

Drug interactions

Concomitant administration of vancomycin and anesthetic agents has been associated with erythema, histamine-like flushing, and anaphylactoid reactions.

Concurrent and/or sequential systemic or topical use of other potentially neurotoxic and/or nephrotoxic drugs such as amphotericin B, aminoglycosides, bacitracin, polymyxin B, colistin, viomycin, or cisplatin, when indicated, requires careful monitoring.

Presentation

Zermacin sterile lyophilized powder for solution for I.V. infusion is available in packs of 1 or 10 vials containing 0.5 g or 1 g vancomycin.

Storage conditions

Store below 30°C. Protect from light.

ARWAN Pharmaceutical Industries Lebanon s.a.l., Jadra, Lebanon

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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