FRONT

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

TEICOPLANIN FOR INJECTION

TECOWEM® Injection

COMPOSITION :
Each vial contains :
Sterile Teicoplanin.....200mg
(Lyophilized)

COMPOSITION :
Each vial contains :
Sterile Teicoplanin.....400mg
(Lyophilized)

DESCRIPTION :
TEICOPLANIN belongs to a group of antibiotics called glycopeptides. Bacteria have an external cell wall that is reinforced by molecules called peptidoglycans. The cell wall is vital for protection against the normal environment of the body in which the bacteria live. TEICOPLANIN works by blocking the formation of these peptidoglycans. By doing this the walls of the bacteria become weak and this results in the death of the bacteria. TEICOPLANIN is used to treat serious infections of the heart and blood. It is not absorbed from the gut and is therefore only given by injection or infusion.

PHARMACOLOGICAL ACTION :
Lyophilized TEICOPLANIN is a bactericidal, glycopeptide antibiotic, produced by fermentation of Actinoplanes teicomyceticus. It is active in vitro against both aerobic and anaerobic Gram-positive bacteria.
Species usually sensitive :
Staphylococcus aureus, coagulase negative staphylococci (sensitive or resistant to methicillin), streptococci, enterococci, Listeria monocytogenes, micrococci group, corynebacteria, Gram-positive anaerobes including Clostridium difficile and peptococci.
Species usually resistant : Nocardia asteroides, lactobacillus spp., Leuconostoc and all Gram-negative bacteria.Bactericidal synergy has been demonstrated in vitro, in combination with aminoglycosides, against group D streptococci and staphylococci. In vitro combinations of TEICOPLANIN with rifampicin or fluorinated quinolones show primarily additive effects and sometimes synergy. One-step resistance to TEICOPLANIN could not be obtained in vitro, and multi-step resistance was only reached in vitro after 11 to 14 passages. TEICOPLANIN does not show cross-resistance with other classes of antibiotics. Following intravenous and intramuscular administration, TEICOPLANIN is widely distributed in body tissues. It is slowly eliminated with a plasma half-life of 70 to 100 hours; the excretory route is renal. TEICOPLANIN is not absorbed when administered orally. TEICOPLANIN does not penetrate through the blood-brain barrier

INDICATIONS :
TEICOPLANIN is indicated in potentially serious Gram-positive infections, including those which cannot be treated with other antimicrobial drugs. The effectiveness of TEICOPLANIN has been documented in the following infections caused by organisms sensitive to TEICOPLANIN: Endocarditis, Septicaemia, Osteomyelitis, Respiratory infections, Skin and soft tissue infections, Urinary tract infections and Peritonitis associated withChronic Ambulatory Peritoneal Dialysis (CAPD).

CONTRA-INDICATIONS :
Hypersensitivity to TEICOPLANIN. Safety and efficacy has not been established in children under three years of age.TEICOPLANIN should not be used during pregnancy and lactation, as safety has not been established. It is not known whether TEICOPLANIN passes into breast milk.TEICOPLANIN must not be injected into the subarachnoid space.

WARNINGS :
TEICOPLANIN should be administered with caution in patients known to be hypersensitive to vancomycin since cross hypersensitivity may occur. However, a history of "Red Man Syndrome" which can occur with vancomycin, is not a contra-indication to TEICOPLANIN. Thrombocytopenia has been reported with TEICOPLANIN, especially at doses higher than those usually recommended. It is advisable for periodic haematological studies to be performed during treatment. Liver and renal function tests are recommended during treatment.Serial renal and auditory function tests should be undertaken in the following circumstances:Prolonged treatment in patients with renal insufficiency.Concurrent and sequential use of other drugs which may have neurotoxic and/or nephrotoxic properties. These include aminoglycosides, colistin, amphotericin B, cyclosporin, cisplatin, furosemide and ethacrynic acid. However, there is no evidence of synergistic toxicity when TEICOPLANIN is used in combination with the above drugs.

DOSAGE AND DIRECTIONS FOR USE :
The reconstituted TEICOPLANIN injection may be administered either intravenously or intramuscularly. The

BACK

intravenous injection may be administered either as a bolus or as a 30 minute infusion. Dosage is usually once daily but, in cases of severe infection, a second injection should be administered on the first day in order to reach the required serum concentrations more rapidly.The majority of patients, with infections caused by organisms sensitive to the antibiotic, show a therapeutic response within 48 to 72 hours. The duration of therapy is determined by the type and severity of the infection, and the clinical response of the patient. In endocarditis and osteomyelitis, treatment for three weeks or longer is recommended.

THERAPEUTIC DOSAGE : Adults and elderly patients with normal renal function:
Prophylaxis : 400mg intravenously as a single dose at induction of anaestheisa.
Moderate infections : Skin and soft tissue infections, urinary tract infections, lower respiratory tract infections.
Loading dose : One single I.V. injection of 400 mg (two vials) on the first day.
Maintenance dose : A single I.V. or I.M. injection of 200 mg daily.
Severe infections : Joint and bone infections, septicaemia, endocarditis.
Loading dose : 400 mg I.V. injection every 12 hours for the first three doses.
Maintenance dose : A single I.V. or I.M. injection of 400 mg daily. In some clinical situations, such as infected, severely burned patients or Staphylococcus aureus endocarditis, unit maintenance doses of up to 12 mg per kg may be required. Note: Standard doses of 200mg and 400 mg are equivalent to mean doses of 3 mg per kg and 6 mg per kg respectively. In overweight patients the recommended dose for moderate infections is 3 mg per kg and for severe infections is 6 mg per kg.
Children : TEICOPLANIN can be used to treat Gram-positive infections in children from the age of three years. For severe infections and neutropenic patients the recommended dose is 10 mg per kg every 12 hours, by intravenous injection, for the first three doses. Thereafter a dose of 10 mg per kg should be administered by either intravenous or intramuscular injection as a single dose each day. For moderate infections the recommended dose is 10 mg per kg. by intravenous injection, every 12 hours for the first three doses. Thereafter a dose of 6 mg per kg should be administered by either intravenous or intramuscular injection as a single dose each day.

IN CONTINUOUS AMBULATORY PERITONEAL DIALYSIS
After a single loading IV dose of 400mg If the patient is febrile, the recommended dosage is 20mg/1 per bag in the first week, 20mg/1 in alternate bags in the second week and 20mg/1 in the overnight dwell bag only during the third week.

Adults and elderly patients with renal insufficiency
For patients with impaired renal function, reduction of dosage is not required until the fourth day of TEICOPLANIN treatment.

From the fourth day of treatment

In mild renal insuffiency
Creatinine clearance between 40 and 60ml/min and in haemodialysed patients, TEICOPLANIN dose should be one third of the normal either by administering the initial unit dose every third day, or by administering one third of this dose once a day.

In severe renal insufficiency
Creatinine clearance less than 40ml/min and in haemodialysed patients, TECICOPLANIN dose should be one third of normal either by administering the initial unit dose every third day, or by administering one third of this dose once a day. TEICOPANIN is not removed by dialysis.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS :
Occasional hypersensitivity reactions, exanthema, erythema, pruritus, fever, bronchospasm and anaphylactic reactions. Pain at the injection site and phlebitis or the formation of an abscess have been observed occasionally. In some cases a rise in the transaminase and/or alkaline phosphates has been observed. A rise in serum creatinine may also occur.Eosinophilia, thrombocytopenia or leucopenias have been described. TEICOPLANIN can, on rare occasions, lead to nausea and vomiting, headaches or dizziness. Loss of hearing, tinnitus or vestibular disturbances have been observed in patients treated with TEICOPLANIN in combination with a potentially ototoxic drug such as an aminoglycoside.

OVERDOSAGE :
TEICOPLANIN is not removed by haemodialysis. Treatment of overdosage should be symptomatic. Several overdoses of 100mg/kg/day have been administered in error to two neutropenic patients aged 4 and 8 years. Despite high plasma concentration of TEICOPLANIN up to 300mg/ml there were no symptoms or laboratotry abnormaities.

STORAGE :
Store at a temperature below 25°C. Protect from light.

PRESENTATION :
One vial of 200mg in a box.
One vial of 400mg in a box.

KEEP OUT OF THE REACH OF CHILDREN.

Mfg. Lic. No. : NL-MNB/2022/446 & NL-MB/2022/447

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