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

℞

Teicoplanin Injection IP

TEICOTAS ® 200 mg / 400 mg

टाइकोटास ®

For IM / IV use only
Single use vial Lyophilized

Composition:
Each combipack contains:
(A) Teicoplanin Injection IP 200mg
Each vial contains:
Teicoplanin IP..... 200mg
Excipients..... Q.S.
(B) Sterile Water for Injection IP 5mL
Each Plastic Bottle contains:
Sterile Water for InjectionIP.....5mL

Composition:
Each combipack contains:
(A) Teicoplanin Injection IP 400mg
Each vial contains:
Teicoplanin IP..... 400mg
Excipients..... Q.S.
(B) Sterile Water for Injection IP 5mL
Each Plastic Bottle contains:
Sterile Water for InjectionIP.....5mL

DESCRIPTION

Teicoplanin is a bactericidal glycopeptide antibiotic produced by fermentation of *Actinoplanes Teichomycetius.*

It is active in vitro against both aerobic and anaerobic Gram-positive bacteria.

Species usually sensitive to Teicoplanin are *Staphylococcus aureus* and coagulase negative *Staphylococci* (sensitive or resistant to methicillin), *Streptococci; entercocci, Listeria monocytogenes; micrococci; Elkenelia corrodens, group JK corynebacteria* and Gram-positive anaerobes including *Clostridium difficle* and *peptococci***.**

Species usually sensitive:

Staphylococcus aureus coagulase negative *Staphylococci* (sensitive or resistant to methicillin), *Streptococci; entercocci, Listeria monocytogenes; micrococci; group JK corynebacteria* and Gram-positive anaerobes including *Clostridium difficle* 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 11to 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 e.g. penicillins and cephalosporins. Skin and tissue infections, joint and bone infections, lower respiratory tract infections, septicaemia, peritonitis related to continuous ambulatory peritoneal dialysis, endocarditis and urinary tract infections.

DOSAGE AND ADMINISTRATION

The reconstituted Teicoplanin injection can be administered and either intravenously or intramuscularly. Intravenous dosing may be rapid injection over one minute or by a slow infusion over 30 minutes.

Dosage regimen

Administration

The reconstituted Teicoplanin injection may be administered directly either intravenously or intramuscularly. The 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 more rapidly the required serum concentrations.

The majority of patients with infections caused by organisms sensitive to the antibiotic show a therapeutic response within 48-72 hours. The total 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.

Determination of Teicoplanin serum concentrations may optimise therapy. In severe infections, trough serum concentrations should not be less than 10mg/L. Peak concentrations measured one hour after a 400mg intravenous dose are usually in the range of 20-50mg/L; peak serum concentrations of up to 250mg/L have been reported after intravenous doses of 25mg/kg A relationship between serum concentration and toxicity has not been established.

Therapeutic dosage:

Adults and elderly patients with normal renal function:

Prophylaxis: 400mg intravenously as a single dose at induction of anaesthesia

Moderate infections: Skin and soft tissue infections, urinary tract infections, lower respiratory tract infections.

Loading dose: One single IV injection of 400 mg (two vials) on the first day. Maintenance dose: A single IV or IV injection of 200 mg daily.

CONTRAINDICATIONS

Teicoplanin should not be administered to patients who have exhibited previous hypersensitivity to teicoplanin.

WARNING AND PRECAUTIONS

Teicoplanin should be administered with caution in patients known to be hypersensitive to vancomycin since cross hypersensitivity may occur. However, a history of the "Red Man Syndrome" that can occur with vancomycin is not a contraindication for Teicoplanin. Thrombocytopenia has been reported with teicoplanin especially at higher doses than those usually recommended. Serial renal and auditory function tests should be undertaken in the circumstances are:

- 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 add. However, there is no evidence of synergistic toxicity when Teicoplanin is used in combination with the above drugs.

DRUG INTERACTIONS

Concurrent and sequential use of other drugs which may have neurotoxic and / or nephrotoxic properties may lead to neurotoxicity or nephrotoxicity. These include amminoglycosides, colistin, amphotericin B, cyclosporine, cisplatin, furosemide and ethacrynic acid. However, there is no evidence of synergistic toxicity with combinations with Teicoplanin

PREGNANCY

Teicoplanin should not be used during confimed or presumed pregnancy unless a physician considers that the potential benefits outweigh any possible risk.

LACTATION

There is no information about the excretion of Teicoplanin in milk or placental transfer of the drug.

ADVERSE EFFECTS

Local reactions: erythema, local pain thrombophlebitis

Allergic: rash, pruritus, severe bronchospasm, anaphylactic reactions

Gastrointestinal: nausea, vomiting, diarrhoea

Blood: eosinophilia, leucopenia, neutopenia, thrombocytopenia, thrombocytosis

Liver function: increases in serum transaminases and/or serum alkaline phosphatase

Renal function: transient elevations of serum creatning

Central nervous system: dizziness and headache.

STORAGE

Storage: Store below 25^{0}C. Protect from light and Moisture.

Keep the medicine out of reach of children.

PRESENTATION

Available in vial of 200 mg / 400 mg.

Manufactured in India by:

Kaliberr BioScience Pvt. Ltd.
Survey No.444/1, Koshimba Road,
Khadki, Lakhmapur, Tal: Dindori, Nashik,
Pin Code - 422202, Maharashtra, India.

Marketed by:

AEQUITAS HEALTHCARE

Aequitas Healthcare Pvt. Ltd.
305, Jaisingh Business Centre,
119, Sahar Road, Andheri (East),
Mumbai - 400 099.

®Registered Trade Mark.
To report product complaint or
Adverse Drug Reaction email us on
care@ahcpl.in

P077D009