For the use only of a registered medical practitioner or hospital or laboratory

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Biocon

Teicoplanin Injection IP 200 mg/400 mg

TECONIN® 200 / TECONIN® 400 टिकोनीन २०० /टिकोनीन ४००

COMPOSITION
TECONIN® 200
Composition:
(A) Teicoplanin injection IP 200 mg
Each vial contains:
Teicoplanin IP (Sterile) 200 mg
Excipients q.s.
(B) Sterile Water for injections IP 5 mL FFS Plastic Ampoule
Each ampoule contains:
Sterile Water for injections IP

TECONIN® 400
Composition:
(A) Teicoplanin injectiosn IP 400 mg
Each vial contains:
Teicoplanin IP (Sterile) 400 mg
Excipients q.s.
(B) Sterile Water for injections IP 5 mL FFS Plastic Ampoule
Each ampoule contains:
Sterile Water for injections IP

ATC Code: J01XA02
Pharmaceutical Form: Lyophilized powder for Injection
Powder for reconstitution for IM/IV use only.

Reconstitute with 3 mL sterile water for injections IP

PHARMACOLOGY
Teicoplanin is a glycopeptide antibiotic that has shown in vitro bactericidal activity against both aerobic and anaerobic gram-positive organisms. Teicoplanin inhibits the growth of susceptible organisms by interfering with cell wall biosynthesis at a site different from that affected by β -lactams. It is active against staphylococci (including those resistant to methicillin and other β-lactam antibiotics), streptococci, enterococci, *Listeria monocytogenes*, corynebacteria and gram-positive anaerobes including *Clostridium difficile* and peptococci.

Bactericidal synergy has been demonstrated *in vitro* with teicoplanin when combined with aminoglycosides against *Staphylococcus aureus* and enterococci; synergism has also been demonstrated with imipenem against these organisms. The *in vitro* combination of teicoplanin and rifampin has shown additive and synergistic effects against Staphylococcus aureus. *In vitro* synergy with ciprofloxacin against *Staphylococcus epidermidis* has also been observed. Teicoplanin does not show cross-resistance with other classes of antibiotics. Some cross-resistance is observed between teicoplanin and the glycopeptide vancomycin among enterococci. Teicoplanin is taken up by leukocytes and macrophages, and retains antistaphylococcal activity within these cells.

Pharmacokinetics: Teicoplanin is administered by parenteral injection. The bioavailability of a single 3-6 mg/kg IM injection is >90%. Following oral administration, teicoplanin is not systemically absorbed from the normal gastrointestinal tract; 40% of the administered dose is present in the feces in a microbiologically active form.

Following IV administration of 3-6 mg/kg, the plasma concentration declines with a terminal elimination half-life of about 150 hrs; total plasma clearance ranges from 11.9-14.7 mL/hr/kg. This long half-life allows once a day administration. At 6 mg/kg administered IV at 0, 12, 24 hrs and every 24 hrs thereafter as 30-min infusion, a predicted trough serum concentration of 10 mg/L would be reached by day 4. Predicted steady-state peak and trough serum concentrations of approximately 64 and 19 mg/L, respectively, would be attained by day 28.

Teicoplanin distributes readily into the skin (subcutaneous fat) and blister fluid, myocardium, pulmonary tissue and pleural fluid, bone and synovial fluid but not readily into cerebrospinal fluid (CSF). It is 90-95% bound with weak affinity to plasma proteins. Steady-state volume of distribution after 3-6 mg/kg IV ranges from 0.94-1.4 L/kg. When administered parenterally, the metabolic transformation is minor, about 3%; about 80% of administered drug is excreted in the urine. Renal clearance after 3-6 mg/kg IV ranges from 10.4-12.1 mL/hr/kg.

INDICATIONS
The effectiveness of teicoplanin has been documented in the following infections:-
skin and soft tissue infections, urinary tract infections, lower respiratory tract infections, joint and bone infections, septicaemia, endocarditis and peritonitis.

CONTRAINDICATIONS
Teicoplanin is contraindicated in patients who have exhibited previous hypersensitivity to the drug.

WARNINGS 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. It is advisable for periodic haematological studies to be performed during treatment. Liver and renal function tests are advised during treatment.

Serial renal and auditory function tests should be undertaken in the following circumstances:
i) Prolonged treatment in patients with renal insufficiency.
ii) 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.

Superinfection as with other antibiotics, the use of teicoplanin, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

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

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

DRUG INTERACTIONS
Teicoplanin should be used with care in conjunction with or sequentially with other drugs with known nephrotoxic or ototoxic potential. Of particular concern are streptomycin, neomycin, kanamycin, gentamicin, amikacin, tobramycin, cephaloridine, colistin.

No adverse interactions were noted when teicoplanin was administered to patients already receiving various medications including other antibiotics, antihypertensives, anaesthetic agents, cardiac drugs and antidiabetic agents.

SIDE EFFECTS
Teicoplanin is generally well tolerated. Side-effects rarely require cessation of therapy and are generally mild and transient: serious side-effects are rare. The following adverse events have been reported:

Local reactions: Erythema, local pain, thrombophlebitis, injection site abscess.

Hypersensitivity: Rash, pruritis, fever, bronchospasm, anaphylactic reactions, anaphylactic shock, rigors, urticaria, angioedema, rare reports of exfolative dermatitis, toxic epidermal necrolysis, rare cases of erythema multiforme including Stevens- Johnson Syndrome. In addition, infusion-related events, such as erythema or flushing of the upper body, have been rarely reported in which the events occurred without a history of previous teicoplanin exposure and did not recur on re-exposure when the infusion rate was slowed and/or concentration decreased. These events were not specific to any concentration or rate of infusion.

Gastric-intestinal: Nausea, vomiting, diarrhoea.
Blood: Eosinophilia, leucopenia, thrombocytopenia, thrombocytosis, neutropenia, rare cases of reversible agranulocytosis.
Liver function: Increases in serum transaminases and/or serum alkaline phosphatase.

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Renal function: Transient elevations of serum creatinine, renal failure.
Central nervous system: Dizziness, headache.
Auditory/vestibular: Mild hearing loss, tinnitus and vestibular disorder.
Other: Superinfection (overgrowth of non-susceptible organisms).
OVERDOSAGE
Teicoplanin is not removed by haemodialysis. Treatment of overdosage should be symptomatic. Despite high plasma concentrations of teicoplanin up to 300 mg/ml there were no symptoms or laboratory abnormalities.

DOSAGE AND ADMINISTRATION
The reconstituted Teicoplanin can be administered either intravenously or intramuscularly. Intravenous dosing may be by rapid injection over five minute or by a slow infusion over 30 minutes. 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. During Intramuscular administration it should not exceed 3ml (400mg) at a single site.
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 infection and the clinical response of the patient. In endocarditis and osteomyelitis, treatment for 3 weeks or longer is recommended.

Adult or elderly patients with normal renal function
Prophylaxis 400 mg intravenously as a single dose at induction of anaesthesia

Moderate infections:
Loading dose: One single IM/IV injection of 400 mg on the first day
Maintenance dose: A single IM/IV injection of 200 mg daily

Severe infections:
Loading dose: Three 400 mg IV injections, administered 12 hours apart Maintenance dose: A single IV or IM 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/kg have been administered (intravenously).

Children (2 months and above)
For severe infections and neutropenic patients
The recommended dose is 10 mg/kg every 12 hours for the first three doses; thereafter a dose of 10mg/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/kg every 12 hours for the first three doses; thereafter a dose of 6mg/kg should be administered by either intravenous or intramuscular injection as a single dose each day.

Neonates
The recommended dosage regimen for neonates is a loading dose of 16 mg/kg followed by a daily dose of 8mg/kg.

In continuous ambulatory periotoneal dialysis
After a single loading IV dose of 400 mg if the patient is febrile, the recommended dosage is 20 mg/L per bag in the first week, 20 mg/L in alternate bags in the second week and 20 mg/L 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. Measurement of the serum concentration of teicoplanin may optimise therapy.

From the fourth day of treatment In mild renal insufficiency:
Creatinine clearance between 40 and 60 mL/min, Teicoplanin dose should be halved, either by administering the initial unit dose every two days, or by administering half of this dose once a day.

In severe renal insufficiency:
Creatinine clearance less than 40 mL/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. Teicoplanin is not removed by dialysis.

NOTE - Important
Shaking this solution causes formation of foam making it difficult to get the expected volume but if teicoplanin has been completely dissolved then the foam does not change the concentration of the solution .

DO NOT SHAKE, Gently roll the vial between the hands until the powder is completely dissolved, paying attention to avoid the formation of foam. If the solution becomes foamy then it should be left to stand for 15 minutes.

ENSURE THAT ALL THE POWDER IS DISSOLVED
It is important that the solution is correctly prepared and carefully withdrawn into the syringe of a carefully prepared solution will be 100mg in 1.5mL (from the 200 mg vial) and 400 mg in 3 mL (from 400 mg vial). The final solution is isotonic with a pH of 7.5.

The reconstituted solution may be injected directly, or alternatively diluted with: 0.9% Sodium Chloride Injection, Ringer-Lactate Solution, 5% Dextrose Injection, 0.18% Sodium Chloride and 4% Dextrose Injection.

COMPATIBILITY
Solutions of teicoplanin and aminoglycosides are incompatible when mixed directly and should not be mixed before injection.

Shelf Life: Please refer carton/label.

STORAGE AND HANDLING INSTRUCTIONS
Storage: Store at a temperature below 25°C. Protect from light.
Keep out of reach of children.

After reconstitution:
In keeping with good clinical pharmaceutical practice reconstituted vials of Teicoplanin should be used immediately and any unused portion discarded. On the few occasions when changing circumstances make this impractical reconstituted solution should be kept at 2°C - 8°C and discarded within 24 hours. Do not store in a syringe.

Special Precautions for disposal and other handling:
Any unused medicinal product should be disposed off in accordance with the local requirements.

HOW SUPPLIED :
TECONIN® 200 mg and TECONIN® 400 mg are available in vial with Sterile water for injections IP 5 mL FFS Plastic Ampoule.

BF/LL/3988/01

Marketed by:
Biocon Biologics India Limited
Biocon House, Semicon Park, Electronics City, Phase - II, Bengaluru - 560 100, India.

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To report adverse events and/or product complaints visit our website **www.biocon.com** or call toll free No.: **1800 102 9465** or e mail us at **drugsafety@biocon.com**