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Teicoplanin Injection I.P. 400mg

TICOBRAVE™

FOR IV/IM USE

(Lyophilized Powder)

DESCRIPTION

Teicoplanin Injection I.P. is a parenteral antibiotic having mainly bactericidal activity. It can be administered once daily by either intramuscular or intravenous routes. The active principle of Teicoplanin is a novel glycopeptide. It is active against both aerobic and anaerobic gram-positive bacteria. Species usually sensitive *Staphylococcus aureus* and coagulate negative *staphylococci* (sensitive or resistant to methicilin), *streptococci, enterococci, Listeria monocytogenes, Micro cocci* group and gram-positive anaerobes including *Clostridium difficile* and *peptococci*. The spectrum of activity is similar to Vancomycin. Due to its mechanism of action the emergence of strains resistant to teicoplanin is unlikely gram-positive bacteria which show resistance to penicillin and cephalosporin, macrolides, tetracycline and chloramphenicol aminoglycosides or rifampicin remain sensitive to teicoplanin is widely distributed in body tissue. It is slowly eliminated with a plasma terminal elimination half-life of about 150 hours, the excretory route is renal. Teicoplanin is not absorbed when administered orally.

COMPOSITION :

Each vial contains :

Teicoplanin I.P. 200 mg.
(Sterile Lyophilized Powder)

Each vial contains :

Teicoplanin I.P. 400 mg.
(Sterile Lyophilized Powder)

INDICATIONS :

Teicoplanin Injection I.P. is indicated in potentially serious gram-positive infections including those which cannot be treated with antimicrobial drugs penicillins and cephalosporins. Teicoplanin Injection I.P. is useful in the therapy of serious staphylococcal infections in patients who can not receive or who have failed to respond to the penicillins and cephalosporins, or who have infections with *staphylococci* resistance to other antibiotics. The effectiveness of Teicoplanin Injection I.P. has been documented in the following infections :

1) Skin and soft tissue infections, 2) Urinary tract infections, 3) Lower respiratory tract infections, 4) Joint and bone infections, 5) Septicemia endocarditis, 6) Peritonitis related to continuous ambulatory peritoneal dialysis.

Teicoplanin Injection I.P. may be used for antimicrobial prophylaxis in orthopedic surgery at risk of gram-positive bacteria.

PRESENTATION :

Teicoplanin Injection I.P. is presented in vials containing teicoplanin each with an ampoule containing the appropriate volume of Sterile Water for Injections. An injections containing the full dose of 200 mg or 400 mg teicoplanin will be obtained if all the reconstituted solution is withdrawn from the vial by a syringe. Vials do not contain any preservative.

METHOD OF PREPARATION :

The solution is reconstituted by adding 3.14 mL of Sterile Water for Injections to the 200 mg and 400 mg powder vial. The water is slowly added to the vial which should be rotated until all the powder is dissolved to avoid

foaming. If foam is developed, allow the solution to stand for approximately 15 minutes so that the foam disappears. Only clear and yellowish solutions should be used.

Nominal teicoplanin content of vial	200 mg	400 mg
Volume of powder vial	10 mL	22 mL
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	3.0 mL	3.0 mL

The reconstituted solution may be injected directly or alternatively further diluted.

Preparation of the diluted solution before infusion:

Teicoplanin can be administered in the following infusion solutions

- Sodium chloride 9 mg/mL (0.9%) solution
- Ringer solution
- Ringer-lactate solution
- 5% dextrose injection
- 10% dextrose injection
- 0.18% sodium chloride and 4% glucose solution
- 0.45% sodium chloride and 5% glucose solution
- Peritoneal dialysis solution containing 1.36% or 3.86% glucose solution.

Any unused product or waste material should be disposed of in accordance with local requirements.

DOSAGE AND ADMINISTRATION :

The reconstituted Teicoplanin Injection I.P. can be administered either intravenous or intramuscular. Intravenous dosing may be by rapid injection over one minute or more slowly by infusion over 30 minutes. Dosage is usually once daily but a second dose may be given on the first. The majority of patients with infections caused by organisms sensitive to the antibiotic show a 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 3 weeks or longer is recommended.

Determination of Teicoplanin Injection I.P. serum concentration may optimize therapy. In severe infections, trough serum concentrations should not be less than 10 mg/available assay.

THERAPEUTIC DOSAGE :

Adult or elderly patients with normal renal function:

- *Orthopedic prophylaxis:* 400 mg intravenously as a single dose at induction of anesthesia.
- *Moderate infections:* skin and soft tissue infection, lower respiratory tract infection.

  1) Loading dose: one single intravenous injection of 400 mg daily.

  2) Maintenance dose: a single intravenous or intramuscular injection of 200 mg daily.
- *Severe infections:* joint and bone infection, septicemia, endocarditis.

  1) Loading dose: 400 mg intravenous injection every 12 hours for the first three doses.

  2) Maintenance dose: a single intravenous or intramuscular injection of 400 mg daily. In some clinical situation, such as infected, severely burned patients or *Staphylococcus aureus* endocarditis, unit maintenance doses of up to 12 mg/kg may be required.

Standard doses of 200 mg and 400 mg equate respectively to mean doses of 3 and 6 mg/kg. In patients weighing more than 85 kg it is recommended to adapt the dosage to the weight following the same therapeutic schedule; moderate infections 3 mg/kg, severe infections 6 mg/kg.

Children:

Teicoplanin Injection I.P. can be used to treat gram positive infections in children from the age of 2 months. For severe infections and neutropenic patients the recommended dose is 10 mg/kg every 12 hours by intravenous injection for the first three doses, thereafter a dose of 10 mg/kg should be administered by intravenous injection as a single dose each day. For moderate infections the recommended dose is 10 mg/kg by intravenous injections every twelve hours for the first three doses, thereafter a dose of 6 mg/kg should be administered by either intravenous or intramuscular injection as a single dose each day.

Neonates :

The recommended dosage for neonates is single loading dose of 16 mg/kg on the first day of treatment followed on subsequent days by maintenance doses of 8 mg/kg once daily. The doses should be given as intravenous infusion over thirty minute.

Adult And Elderly Patients With Renal Impairment :

For patients with impaired renal function, reduction of dosage is not required until the fourth day of Teicoplanin treatment. Measurement of the concentration of Teicoplanin injection I.P. may optimize therapy.

From the Fourth day of Treatment :

In mild renal insufficiency :

Creatinine clearance b/w 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, 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. Teicoplanin is not removed by dialysis.

In continuous ambulatory peritoneal 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.

CONTRAINDICATIONS :

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

WARNINGS AND PRECAUTIONS :

Teicoplanin Injection I.P. 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 to Teicoplanin Injection I.P. Thrombocytopenia has been reported with Teicoplanin Injection I.P. especially at higher doses than those usually recommended. It is advisable to do periodic hematological studies and liver and renal function tests are advised during treatment. Serial renal and auditory function tests should be undertaken in the following circumstances:

- Prolonged treatment in the patients with renal insufficiency
- Concurrent and sequential use of other drugs which may have nephrotoxic and/or ototoxic properties. These include cisplatin, frusemide and ethacrynic acid. Dosage must be adapted in patients with renal impairment.

USE IN PREGNANCY / LACTATION :

Although animal reproduction studies have not shown to have teratogenic effects, Teicoplanin should not be used during confirmed or presumed pregnancy unless a physician considers that the potential benefits outweigh any possible risk. There is no information about the excretion of Teicoplanin in milk or potential transfer of the drug.

INTERACTIONS :

During clinical trials, Teicoplanin Injection I.P. was administ association with different categories of drugs including other antibio hypertensive, anesthetic agents, cardiac drugs and anti diabetic without finding any evidence of interaction.

Teicoplanin and aminoglycoside are incompatible when mixed dire must not be mixed before injection. If teicoplanin is administ combination therapy with other antibiotics, the preparation m administered separately.

OVERDOSAGE :

Treatment of over dosage should be symptomatic. Several over dos 100 mg/kg/day have been administered in error to two neutropenic pe patients aged 4 and 8 years. Despite high plasma concentrati Teicoplanin Injection I.P. up to 300 mg/L there were no sympto laboratory abnormality. Teicoplanin is not removed by dialysis.

SIDE EFFECTS :

Teicoplanin Injection I.P. is generally well tolerated. Side effects require cessation therapy and are generally mild and transient. seriou effect are rare.

The following adverse events have been reported :

Local reaction : erythema, local pain, thrombophlebitis.

Allergic : rash, pruritus, fever, bronchospasm, anaphylactic reaction.

Gastrointestinal: nausea, vomiting, diarrhea.

Blood : eosinophilia, leucopenia, neutropenia, Thrombocytop thrombocytosis.

Liver function : increase in serum transaminase and/or serum al phosphatase

Renal function: transient elevations of serum creatinine.

Central nervous system : dizziness and headache.

Other reported events with an unknown causal relationship are mild he loss, tinnitus and vestibular disorder.

STORAGE :

Store in a dry place below 25°C. Protect from light.

From a microbiological point of view, the medicinal product should be immediately. If not used immediately, in-use storage times and cond prior to use are the responsibility of the user and would normally n longer than 24 hours at 2°C to 8°C, unless reconstitution has taken pl controlled and validated aseptic conditions.

HOW SUPPLIED :

Ticobrave 200 mg, Ticobrave 400 mg

TM - Trademark Under Registration

Mfd. by Protech Telelinks
(A WHO-GMP Certified Co.)
Makuta Dgt. Solvent Road, Kala Amb,
Distt. Sirmour-173030 (H.P.)

Marketed by