Tigecycline for injection USP 50 mg / vial (Lyophilized)

Tizigen™

Composition: Each vial contains:
Tigecycline USP ……50 mg
Excipients ……..q.s.

Route of administration: Intravenous.

Pharmaceutical form: Powder for Injection (Lyophilized).

Pharmacological Action: Tigecycline is an antibiotic indicated for the treatment of complicated intra-abdominal infections and infections of the skin and soft tissues caused by gram-positive, gram-negative bacteria and anaerobic microorganisms.

Pharmacokinetics: Tigecycline administered intravenously has a bioavailability of 100%. Its binding to plasma proteins in vitro is approximately between 71% and 89%. Pharmacokinetic studies in animals and humans have shown that tigecycline is widely distributed to tissues. On average, less than 20% of the administered dose of tigecycline is metabolized by the liver prior to excretion. Approximately 59% of the administered dose of tigecycline is eliminated by biliary and fecal excretion and 33% by urine.

Indications and use: Tigecycline is indicated in adult patients and in children from eight years of age for the treatment of complicated skin and soft tissue infections (excluding diabetic foot infections) and complicated intra-abdominal infections. Tigecycline should be used only in situations where alternative antibiotics are not suitable for treating such infections.

Dosage and administration:
Adults: The recommended starting dose for adults is 100 mg, followed by a 50 mg dose every 12 hours, over a period of 5 to 14 days. The duration of treatment should be established according to the severity, the site of the infection and the clinical response of the patient.
Pediatric Patients (8 to 12 years old):
Children 8 to 12 years of age: It is recommended to administer a dose of 1.2 mg / kg intravenously every 12 hours up to a maximum dose of 50 mg every 12 hours for a period of 5 to 14 days.
Adolescents 12 to 17 years of age: It is recommended to administer a dose of 50 mg every 12 hours for a period of 5 to 14 days.
The use of tigecycline in pediatric patients should be limited to those clinical situations in which no alternative antibacterial treatment is available.
The duration of treatment must be established by a doctor. If symptoms persist or worsen during treatment, see a doctor.

Method of reconstitution: Reconstitute each vial with 5.0 mL of 0.9% Sodium Chloride solution, 5% Dextrose solution or Lactated Ringer's solution. The solution obtained will have a concentration of 10 mg / mL of tigecycline. The vial should be gently shaken until the powder dissolves. 5 mL of the reconstituted solution should be withdrawn immediately from the vial and added to a 100 mL intravenous infusion bag or other suitable infusion container. Visually examine for particulate matter or changes in particle color prior to administration. Once reconstituted, Tizigen may be stored at room temperature for up to 24 hours (up to 6 hours in the vial and the remaining time in the intravenous bag).

Tigecycline must be administered intravenously through a specific track or via a Y-track for a period of 30 to 60 minutes. This medicine should only be used for the administration of a single dose; Any unused medicine or other material must be discarded.

Contraindications: Known hypersensitivity to tigecycline, tetracyclines or any of the components of the formulation. Do not administer in children under 8 years of age.

Warnings and precautions: The administration of tigecycline can lead to the proliferation of microorganisms that are not sensitive to it (including fungi), causing superinfections. Patients should be carefully monitored during therapy and if superinfection occurs, appropriate measures should be taken. Following the use of tigecycline, anaphylactic / anaphylactoid reactions have been reported. It is recommended to administer with caution in patients with hepatic dysfunction and hepatic insufficiency, since the use of tigecycline can worsen their condition.

Adverse Reactions: The most common drug-related adverse reactions occurring after initiation of treatment were nausea, vomiting, and diarrhea. These reactions were reversible, occurred early, and were generally mild or moderate in intensity. Adverse effects including sepsis / septic shock, pneumonia, abscesses, infections, prolonged prothrombin time, hypoglycemia, hypoproteinemia, and dizziness were also observed. Cases of pseudomembranous colitis have been observed, the severity of which can range from mild to moderate. Tigecycline can be associated with permanent tooth staining if used during the development of teething.

Overdosage: No specific information is available for the treatment of overdose with tigecycline. Intravenous administration of a single 300 mg dose of tigecycline over 60 minutes in healthy volunteers resulted in increased nausea and vomiting. Tigecycline is not removed in significant amounts by hemodialysis.

Drug Interactions: Concomitant administration of tigecycline and warfarin may decrease the clearance of warfarin and increase its plasma concentrations. When tigecycline is co-administered with anticoagulants, coagulation tests should be performed frequently. The concomitant use of antibiotics with oral contraceptives may decrease the effectiveness of oral contraceptives. Administration of P-gp (P-glycoprotein substrate) inhibitors (eg ketoconazole or cyclosporin) or P-gp inducers (eg rifampicin) can affect the pharmacokinetics of tigecycline.

Pregnancy and Lactation: Administration of tigecycline is not recommended during pregnancy and / or lactation period.

Storage: Store in a cool and dry place, not more than 25°C. Protect from light.

Keep out of reach of children.

Sale under medical prescription.

Presentation: Box containing 1 Vial of Tigecycline for injection + 1 Ampoule of 5 mL Saline solution.

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Manufactured in India by:
Caplin Point Laboratories Ltd.,
R.S. No.: 85/3, Suthukeny Village,
Mannadipet Commune Panchayat,
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GALENGEN
Marketed by : **Galengen Lifesciences Pvt. Ltd.,**
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