Know The Product (KTP)

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

This information is intended for use by health professionals only

Tigecycline for Injection USP

TIGALIN 50

For I.V. infusion only

Composition:

Each vial contains:

Tigecycline USP 50 mg

Description:

TIGALIN 50 is orange lyophilized powder or cake for Injection.

Indications and Clinical Use:

TIGALIN 50 is indicated for the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

- **Complicated skin and skin structure infections (cSSSI)** caused by Escherichia coli, Enterococcus faecalis (vancomycin-susceptible strains only), Staphylococcus aureus (methicillin-susceptible and -resistant strains), Streptococcus agalactiae, Streptococcus anginosus, Streptococcus pyogenes, Enterobacter cloacae, Klebsiella pneumoniae, and Bacteroides fragilis.

- **Complicated intra-abdominal infections (cIAI)** caused by Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis (vancomycin-susceptible strains only), Staphylococcus aureus (methicillin-susceptible only), Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Bacteroides fragilis, Bacteroides thetaiotaomicron, Bacteroides uniformis, Bacteroides vulgatus, Clostridium perfringens, and Peptostreptococcus micros.

- **Community acquired pneumonia (CAP)** (mild to moderate infections only) caused by Haemophilus influenzae, Streptococcus pneumoniae (penicillin-susceptible isolates only), Mycoplasma pneumoniae, and Chlamydia pneumoniae.

Method of administration:
Intermittent Infusion: Reconstitute each vial with 5 mL of 0.9% NaCl or dextrose 5% in water (D5W) to achieve a concentration of 10 mg/mL. Reconstituted solution should be yellow to orange in color. Do not administer solutions that are discolored or contain particulate matter.

Dilution:

Withdraw 5 mL of the reconstituted solution from the vial and add to a 100 mL IV bag for infusion (for a 100 mg dose, reconstitute two vials; for a 50 mg dose, reconstitute one vial).

The maximum concentration in the IV bag should be 1 mg/mL. The reconstituted solution should be yellow to orange in color; if not, the solution should be discarded.

When administered through a Y-site, Tigecycline is compatible with the following drugs or diluents when used with either 0.9% Sodium Chloride Injection, or 5% Dextrose Injection:

- Dopamine HCl Injection (1.6 mg/mL in 0.9% Sodium Chloride Injection)
- Lidocaine HCl Injection (2.0 mg/mL in 0.9% Sodium Chloride Injection)
- Lactated Ringer's Injection (250 mL bag)
- Potassium Chloride Injection concentrate (0.04 mEq/mL in 0.9% Sodium Chloride Injection)
- Ranitidine Injection (0.6 mg/mL in 0.9% Sodium Chloride Injection)
- Theophylline (1.6 mg/mL in 5% Dextrose Injection)
- Dobutamine Injection (1.0 mg/mL in 0.9% Sodium Chloride Injection)
- Amikacin sulphate Injection (2.5 mg/mL and 5.0 mg/mL in 0.9% Sodium Chloride Injection)
- Gentamicin Injection (1.4 mg/mL in 0.9% Sodium Chloride Injection)
- Tobramycin Injection (1.4 mg/mL in 0.9% Sodium Chloride Injection)
- Haloperidol Injection (0.2 mg/mL in 0.9% Sodium Chloride Injection)
- Metoclopramide Injection (3 mg/mL in 0.9% Sodium Chloride Injection)
- Morphine sulphate Injection (0.5 mg/mL in 0.9% Sodium Chloride Injection)
- Norepinephrine bitartrate Injection (4 mcg/mL in 5% Dextrose Injection)

- Propofol Injectable Emulsion 1% (10 mg/mL in 0.9% Sodium Chloride Injection)
- Piperacillin sodium /tazobactam sodium (EDTA formulation) powder for injection
- (Piperacillin 40 mg/tazobactam 5 mg/mL in 0.9% Sodium Chloride Injection)

The following drugs should not be administered simultaneously through the same Y-site as Tigecycline:

- Amphotericin B
- Amphotericin B lipid complex
- Diazepam
- Esomeprazole
- Omeprazole

General Dosage and Administration:

The recommended dosage regimen for Tigecycline is an initial dose of 100 mg, followed by 50 mg every 12 hours. Intravenous infusions of Tigecycline should be administered over approximately 30 to 60 minutes every 12 hours.

The recommended duration of treatment with Tigecycline for complicated skin and skin structure infections or for complicated intra-abdominal infections is 5 to 14 days. The recommended duration of treatment with Tigecycline for community-acquired bacterial pneumonia is 7 to 14 days. The duration of therapy should be guided by the severity and site of the infection and the patient's clinical and bacteriological progress.

Hepatic Impairment:
No dosage adjustment is warranted in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the

initial dose of Tigecycline should be 100 mg followed by a reduced maintenance dose of 25 mg every 12 hours. Patients with severe hepatic impairment should be treated with caution and monitored for treatment response.

Renal Impairment:

No dosage adjustment is necessary in patients with renal impairment or in patients undergoing haemodialysis.

Paediatric Population

The safety and efficacy of Tigecycline in children under 8 years of age have not been established. Tigecycline is only to be used to treat patients aged 8 years and older after consultation with a physician with appropriate experience in the management of infectious diseases.

Warning and Precautions:

- Anaphylaxis/anaphylactic reactions have been reported with Tigecycline, and may be life threatening.
- During antibiotic therapy, colonization or superinfection with Candida, Proteus or Pseudomonas spp may occur in the GI, genitourinary, and respiratory tracts. Patients should be carefully monitored during therapy. If superinfection occurs, appropriate measures should be taken.
- Tigecycline is not indicated for the treatment of diabetic foot infections. The safety and efficacy of Tigecycline in patients with diabetic foot infections have not been established.
- Tigecycline is not indicated for the treatment of severe community acquired pneumonia. Safety and efficacy of Tigecycline in severe community acquired pneumonia have not been studied.

- Tigecycline is not indicated for treatment of hospital acquired pneumonia (HAP) or ventilator-associated pneumonia. The safety and efficacy of Tigecycline in patients with HAP have not been established.
- Clostridium difficile-associated disease (CDAD) has been reported with use of many antibacterial agents, including Tigecycline. CDAD may range in severity from mild diarrhea to fatal colitis.
- Prescribing Tigecycline in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.
- There are no adequate and well-controlled studies of Tigecycline in pregnant women. Tigecycline should not be used unless the potential benefit to the mother outweighs any possible risk to the fetus.
- Tigecycline has decreased in vitro activity against Proteus spp., Providencia spp., and Morganella spp. Pseudomonas aeruginosa is inherently resistant to Tigecycline**.**

Drug Interactions:

- Based on an in vitro study tigecycline is a P-gp substrate. Co-administration of P-gp inhibitors (e.g., ketoconazole) or P-gp inducers (e.g., rifampicin) could affect the pharmacokinetics of tigecycline.
- Tigecycline is not extensively metabolised. Therefore, clearance of Tigecycline is not expected to be affected by active substances that inhibit or induce the activity of the CYP450 isoforms. In vitro, Tigecycline is neither a competitive inhibitor nor an irreversible inhibitor of CYP450 enzymes.
- No dosage adjustment is necessary when Tigecycline is administered with Digoxin.

- Concomitant administration of Tigecycline (100 mg followed by 50 mg every 12 hours) and warfarin (25 mg single-dose) to healthy subjects resulted in a decrease in clearance of R-warfarin and S-warfarin by 40% and 23%, and an increase in AUC by 68% and 29%, respectively. Tigecycline did not significantly alter the effects of warfarin on INR. In addition, warfarin did not affect the pharmacokinetic profile of Tigecycline. However prothrombin time or other suitable anticoagulation test should be monitored if Tigecycline is administered with warfarin.

Storage and Handling Instructions:

TIGALIN 50 should be stored in dry place below 30^0C. Reconstituted solution must be immediately transferred and further diluted for I.V. infusion and the unused portion of solution should be discarded.

National Healthcare

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