pharmaniaga

Tigaciv 50mg

Lyophilized powder for concentrate for solution for infusion

1. NAME OF THE MEDICINAL PRODUCT

Tigaciv 50mg Lyophilized powder for concentrate for solution for infusion.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml tigecycline vial contains 50 mg of tigecycline lyophilized powder for intravenous infusion. The pH is adjusted with hydrochloric acid, and if necessary sodium hydroxide. After reconstitution, 1 ml contains 10 mg of tigecycline.

3. PHARMACEUTICAL FORM

Tigecycline 50 mg sterile, lyophilized powder for intravenous infusion is a lyophilized orange to orange red cake or powder.

The reconstituted solution should be orange to orange-red; if not, the solution should be discarded. Parenteral drug products should be inspected visually for particulate matter and discoloration (e.g., green or black) prior to administration whenever solution and container permit.

For reconstitution refer to section 6.5.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tigecycline is indicated for the treatment of the following infections caused by susceptible strains of the designated microorganisms in the conditions listed below for patients 18 years of age and older:

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

Complicated intra-abdominal infections caused by *Citrobacter freundii, Enterobacter cloacae, E. coli, Klebsiella oxytoca, Klebsiella pneumoniae, Enterococcus faecalis* (vancomycin-susceptible isolates), *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates 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.*

Appropriate specimens for bacteriological examination should be obtained in order to isolate and identify the causative organisms and to determine their susceptibility to tigecycline. Tigecycline may be initiated as empiric monotherapy before results of these tests are known.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of tigecycline and other antibacterial drugs, tigecycline should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

4.2 Posology and method of administration

The recommended dosage regimen for tigecycline is an initial dose of 100 mg, followed by 50 mg every 12 hours. Intravenous (IV) 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 duration of therapy should be guided by the severity and site of the infection and the patient's clinical and bacteriological progress.

Use in patients with renal impairment

No dosage adjustment of tigecycline is necessary in patients with renal impairment or in patients undergoing hemodialysis (see section 5.2).

Use in patients with hepatic impairment

No dosage adjustment is necessary in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B). Based on the pharmacokinetic profile of tigecycline in patients with severe hepatic impairment (Child Pugh C), the dose of tigecycline should be altered to 100 mg followed by 25 mg every 12 hours. Patients with severe hepatic impairment (Child Pugh C) should be treated with caution and monitored for treatment response (see section 5.2).

Use in children

Safety and effectiveness in patients under 18 years of age have not been established. Therefore, use in patients under 18 years of age is not recommended (see section 4.4).

Use in elderly

No dosage adjustment is necessary in elderly patients.

Race and gender

No dosage adjustment is necessary based on race or gender.

Mode of administration

Intravenous infusion

4.3 Contraindications

Tigecycline is contraindicated for use in patients who have known hypersensitivity to tigecycline.

4.4 Special warnings and precautions for use

Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including tigecycline, and may be life-threatening.

Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics. Therefore, tigecycline should be administered with caution in patients with known hypersensitivity to tetracycline class antibiotics.

Tigecycline may be associated with permanent tooth discoloration in the teeth in humans during tooth development.

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of any antibacterial agent.

Caution should be exercised when considering tigecycline monotherapy in patients with complicated intra-abdominal infections (cIAI) secondary to clinically apparent intestinal perforation.

Isolated cases of significant hepatic dysfunction and hepatic failure have been reported in patients being treated with tigecycline.

Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, pancreatitis and anti-anabolic action (which has led to increased BUN, azotemia, acidosis and hyperphosphatemia).

Acute pancreatitis, which can be fatal, has occurred (frequency: uncommon) in association with tigecycline treatment (see section 4.8). The diagnosis of acute pancreatitis should be considered in patients taking tigecycline who develop clinical symptoms, signs, or laboratory abnormalities suggestive of acute pancreatitis. Cases have been reported in patients without known risk factors for pancreatitis. Patients usually improve after tigecycline discontinuation. Consideration should be given to the cessation of the treatment with tigecycline in cases suspected of having developed pancreatitis.

Monitoring of blood coagulation parameters, including blood fibrinogen, is recommended prior to treatment initiation with tigecycline and regularly while on treatment. (See section 4.8)

The safety and efficacy of tigecycline in patients with hospital acquired pneumonia have not been established.

As with other antibiotics preparations, use of this drug may result in overgrowth of non-susceptible organisms, including fungi. Patients should be carefully monitored during therapy. If super infection occurs, appropriate measures should be taken.

4.5 Interaction with other medicinal products and other forms of interaction

No dosage adjustment is necessary when tigecycline is administered with digoxin.

Tigecycline did not significantly alter the effects of warfarin on increased international normalized ratio (INR). In addition, warfarin did not affect the pharmacokinetic profile of tigecycline. However, prothrombin time or other suitable anticoagulation tests should be monitored if tigecycline is administered with warfarin.

In vitro studies in human liver microsomes indicate that tigecycline does not inhibit metabolism mediated by any of the following 6 cytochrome CYP450 isoforms: 1A2, 2C8, 2C9, 2C19, 2D6, and 3A4. Therefore, tigecycline is not expected to alter the metabolism of drugs metabolized by these enzymes. In addition, because tigecycline is not extensively metabolized, clearance of tigecycline is not expected to be affected by drugs that inhibit or induce the activity of these CYP450 isoforms.

Tigecycline is a substrate of P-gp based on an *in vitro* study using a cell line overexpressing P-gp. The potential contribution of P-gp-mediated transport to the *in vivo* disposition of tigecycline is not known. Co-administration of P-gp inhibitors (e.g., ketoconazole or cyclosporine) or P-gp inducers (e.g., rifampicin) could affect the pharmacokinetics of tigecycline.

Concurrent use of antibiotics with oral contraceptives may render oral contraceptives less effective.

Concomitant use of tigecycline and calcineurin inhibitors such as tacrolimus or cyclosporine may lead to an increase in serum trough concentrations of the calcineurin inhibitors. Therefore, serum concentrations of the calcineurin inhibitor should be monitored during treatment with tigecycline to avoid drug toxicity.

Interference with laboratory and other diagnostic tests:

There are no reported drug-laboratory test interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

Tigecycline may cause fetal harm when administered to a pregnant woman. Results of animal studies indicate that tigecycline crosses the placenta and is found in fetal tissues. Decreased fetal weights in rats and rabbits (with associated delays in ossification) and fetal loss in rabbits have been observed with tigecycline.

Tigecycline was not teratogenic in the rat or rabbit.

There are no adequate and well-controlled studies of tigecycline in pregnant women. Tigecycline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Tigecycline has not been studied for use during labor and delivery.

Lactation

It is not known whether this drug is excreted in human milk. Available pharmacodynamic / toxicological data in animals have shown excretion of tigecycline / metabolites in milk. Because many drugs are excreted in human milk, caution should be exercised when tigecycline is administered to a nursing woman (see section 4.4).

Fertility

The effects of tigecycline on fertility in humans have not been studied. Nonclinical studies conducted with tigecycline in rats do not indicate harmful effects with respect to fertility or reproductive performance.

4.7 Effects on ability to drive and use machines

Tigecycline can cause dizziness (see section 4.8), which may impair the ability to drive and/or operate machine.

4.8 Undesirable effects

For patients who received tigecycline, the following adverse reactions were reported:

System Organ Class	Adverse Reaction
Blood and lymphatic system disorders	
Common	Prolonged activated partial thromboplastin time (aPTT), prolonged prothrombin time (PT), thrombocytopenia
Uncommon	Increased international normalized ratio (INR)
Rare	Hypofibrinogenaemia
Immune system disorders	
Frequency undetermined	Anaphylaxis/anaphylactoid reactions
Metabolism and nutrition disorders	
Common	Hypoproteinemia, hypoglycemia, decreased appetite
Nervous system disorders	
Common	Dizziness, headache
Vascular disorders	
Common	Phlebitis
Uncommon	Thrombophlebitis
Respiratory, thoracic and mediastinal disorders	
Common	Pneumonia
Gastrointestinal disorders	
Very common	Nausea, vomiting, diarrhea
Common	Abdominal pain, dyspepsia
Uncommon	Acute pancreatitis
Hepato-biliary disorders	
Common	Elevated aspartate aminotransferase (AST), elevated alanine aminotransferase (ALT)* hyperbilirubinaemia
Uncommon	Jaundice
Frequency undetermined	Cholestasis
*AST and ALT abnormalities in tigecycline-treated patients were reported more frequently in the post-therapy period than in those in comparator-treated patients, which occurred more often on therapy.	
Skin and subcutaneous tissue disorders	
Common	Pruritus, rash
Frequency undetermined	Severe skin reactions, including Stevens-Johnson Syndrome
General disorders and administration site conditions	
Common	Healing abnormal, injection site reaction
Uncommon	Injection site inflammation, injection site pain, injection site edema, injection site phlebitis
Investigations	
Common	Elevated amylase in serum, blood urea increased (BUN)

The most common treatment-emergent adverse reactions in patients treated with tigecycline were nausea and vomiting. In general, nausea or vomiting occurred early (days 1-2).

Discontinuation from tigecycline was most frequently associated with nausea and vomiting.

4.9 Overdose

No specific information is available on the treatment of overdosage with tigecycline. Intravenous administration of tigecycline at a single dose of 300 mg over 60 minutes in healthy volunteers resulted in an increased incidence of nausea and vomiting.

Tigecycline is not removed in significant quantities by hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Tigecycline, a glycylcycline antibiotic, inhibits protein translation in bacteria by binding to the 30S ribosomal subunit and blocking entry of amino-acyl tRNA molecules into the A site of the ribosome. This prevents incorporation of amino acid residues into elongating peptide chains. Tigecycline carries a glycylamido moiety attached to the 9-position of minocycline. The substitution pattern is not present in any naturally occurring or semisynthetic tetracycline and imparts certain microbiologic properties that transcend any known tetracycline-derivative *in vitro* or *in vivo* activity. In addition, tigecycline is able to overcome the two major tetracycline resistance mechanisms, ribosomal protection and efflux. Accordingly, tigecycline has demonstrated *in vitro* and *in vivo* activity against a broad spectrum of bacterial pathogens. There has been no cross resistance observed between tigecycline and other antibiotics. In *in vitro* studies, no antagonism has been observed between tigecycline and other commonly used antibiotics. In general, tigecycline is considered bacteriostatic. At 4 times the minimum inhibitory concentration (MIC), a 2-log reduction in colony counts was observed with tigecycline against *Enterococcus* spp., *Staphylococcus aureus,* and *E. coli.* However, tigecycline has shown some bactericidal activity, and a 3-log reduction was observed against *Neisseria gonorrhoeae.* Tigecycline has also demonstrated bactericidal activity against common respiratory strains of *Streptococcus pneumoniae, Haemophilus influenzae,* and *Legionella pneumophila.*

Susceptibility Test Methods

Dilution Techniques

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations (MICs). These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized procedure based on dilution methods (broth, agar, or microdilution) or equivalent using standardized inoculum and concentrations of tigecycline. For broth dilution tests for aerobic organisms, MICs must be determined using testing medium that is fresh (<12 hours old). The MIC values should be interpreted according to the criteria provided in Table 2.

Diffusion Techniques

Quantitative methods that require measurement of zone diameters also provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. The standardized procedure requires the use of standardized inoculum concentrations. This procedure uses paper disks impregnated with 15 µg tigecycline to test the susceptibility of microorganisms to tigecycline. Interpretation involves correlation of the diameter obtained in the disk test with the MIC for tigecycline. Reports from the laboratory providing results of the standard single-disk susceptibility test with a 15 µg tigecycline disk should be interpreted according to the criteria in Table 2.

Table 2: Susceptibility Test Result Interpretive Criteria for Tigecycline

	Minimum Inhibitory Concentrations (µg/ml)			Disk Diffusion (zone diameters in mm)		
Pathogen	S	I	R	S	I	R
Staphylococcus aureus (including methicillin resistant isolates)	≤ 0.5[a]	-	-	≥ 19	-	-
Streptococcus spp. other than *S. pneumoniae*	≤ 0.25[a]	-	-	≥ 19	-	-
Streptococcus pneumoniae	≤ 0.12[a]	-	-	≥ 21	-	-
Enterococcus faecalis (vancomycin-susceptible isolates only)	≤ 0.25[a]	-	-	≥ 19	-	-
Enterobacteriaceae[b]	≤ 2	4	≥ 8	≥ 19	15-18	≤ 14
Haemophilus influenzae	≤ 1[a]	-	-	≥ 21	-	-
Anaerobes[c]	≤ 4	8	≥ 16	n/a	n/a	n/a
S= Susceptible; I=Intermediate; R=Resistant						
[a] The current absence of resistant isolates precludes defining any results other than "Susceptible." Isolates yielding MIC results suggestive of "Non-susceptible" category should be submitted to reference laboratory for further testing.						
[b] Tigecycline has decreased *in vitro* activity against *Morganella* spp., *Proteus* spp. and *Providencia* spp.						
[c] Agar dilution.						

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone that prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound reaches the concentrations usually achievable; other therapy should be selected.

Quality Control

As with other susceptibility techniques, the use of laboratory control microorganisms is required to control the technical aspects of the laboratory standardized procedures. Standard tigecycline powder should provide the MIC values provided in Table 3. For the diffusion technique using the 15 µg tigecycline disk, laboratories should use the criteria provided in Table 3 to test quality control strains.

Table 3: Acceptable Quality Control Ranges for Susceptibility Testing

QC organism	Minimum Inhibitory Concentrations (µg/ml)	Disk Diffusion (zone diameters in mm)
Staphylococcus aureus ATCC 25923	Not Applicable	20-25
Staphylococcus aureus ATCC 29213	0.03-0.25	Not Applicable
Escherichia coli ATCC 25922	0.03-0.25	20-27
Enterococcus faecalis ATCC 29212	0.03-0.12	Not Applicable
Streptococcus pneumonia ATCC 49619	0.016-0.12	23-29
Haemophilus influenza ATCC 49247	0.06-0.5	23-31
Bacteroides fragilis ATCC 25285	0.12-1	Not Applicable
Bacteroides thetaiotaomicron ATCC29741	0.5-2	Not Applicable
Eubacterium lentum ATCC 43055	0.06-0.5	Not Applicable
Clostridium difficile ATCC 70057	0.12-1	Not Applicable
ATCC = American Type Culture Collection		

The prevalence of acquired resistance may vary geographically and with time tor selected

550 mm

445 mm

Dimensions: 445 x 550 mm
Font : Arial
Size : 10 Pt & 11pt
Substrate: Bible Paper
GSM: 40 gsm
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species, and local information on resistance is desirable, particularly when treating severe infections. The information below provides only approximate guidance on the probability as to whether the microorganism will be susceptible to tigecycline or not.

Susceptible

Gram-positive aerobes:
Enterococcus avium
Enterococcus casseliflavus
Enterococcus faecalis (vancomycin-resistant strains)
*Enterococcus faecalis** (includes vancomycin-susceptible strains)
Enterococcus faecium (vancomycin-susceptible and -resistant isolates)
Enterococcus gallinarum
Listeria monocytogenes
*Staphylococcus aureus** (includes methicillin-susceptible and -resistant strains)
Staphylococcus epidermidis (methicillin-susceptible and -resistant isolates)
Staphylococcus haemolyticus
*Streptococcus agalactiae**
*Streptococcus anginosus**(includes *S. anginosus, S. intermedius, S. constellatus*)
*Streptococcus pneumonia** (penicillin-susceptible isolates)
*Streptococcus pyogenes**
Viridans group streptococci

Gram-negative aerobes:
Acinetobacter baumannii‡
Aeromonas hydrophila
*Citrobacter freundii**
Citrobacter koseri
Enterobacter aerogenes
*Enterobacter cloacae**
*Escherichia coli** (including extended spectrum beta lactamase-producing strains)
Haemophilus influenza (ampicillin-resistant)
Haemophilus parainfluenzae
*Klebsiella oxytoca**
*Klebsiella pneumoniae** (including extended spectrum beta lactamase-producing strains)
*Legionella pneumophila**
Pasteurella multocida
Serratia marcescens
Stenotrophomonas maltophilia

Anaerobic bacteria:
*Bacteroides fragilis**
Bacteroides distasonis
*Bacteroides thetaiotaomicron**
*Bacteroides uniformis**
*Bacteroides vulgatus**
*Clostridium perfringens**
Peptostreptococcus spp.
*Peptostreptococcus micros**
Porphyromonas spp.
Prevotella spp.

Atypical bacteria:
Mycobacterium abscessus
Mycobacterium fortuitum

* Clinical efficacy has been demonstrated for susceptible isolates in the approved clinical indications.

‡ There have been reports of the development of tigecycline resistance in Acinetobacter infections seen during the course of standard treatment. Such resistance appears to be attributable to an MDR efflux pump mechanism. While monitoring for relapse of infection is important for all infected patients, more frequent monitoring in this case is suggested. If relapse is suspected, blood and other specimens should be obtained and cultured for the presence of bacteria. All bacterial isolates should be identified and tested for susceptibility to tigecycline and other appropriate antimicrobials.

Resistant

Gram-negative aerobes:
Pseudomonas aeruginosa

Anaerobic bacteria:
No naturally occurring species have been found to be inherently resistant to tigecycline.

Resistance:

To date there has been no cross-resistance observed between tigecycline and other antibacterial drugs. Tigecycline is less affected by the two major tetracycline resistance mechanisms, ribosomal protection and efflux. Additionally, tigecycline is not affected by resistance mechanisms such as beta-lactamases (including extended spectrum beta-lactamases), target-site modifications, macrolide efflux pumps or enzyme target changes (e.g., gyrase/topoisomerases). However, some ESBL-producing isolates may confer resistance to tigecycline via other resistance mechanisms. Tigecycline resistance in some bacteria (e.g., *Acinetobacter calcoaceticus-Acinetobacter baumannii complex*) is associated with multi-drug resistant (MDR) efflux pumps.

Interaction with Other Antimicrobials

In *in vitro* studies, no antagonism has been observed between tigecycline and any other commonly used antibiotic class.

5.2 Pharmacokinetic properties

Absorption

Tigecycline is administered intravenously, and therefore has 100% bioavailability.

Distribution

The *in vitro* plasma protein binding of tigecycline ranges from approximately 71% to 89%. Animal and human pharmacokinetic studies have demonstrated that tigecycline readily distributes to tissues.

Metabolism

Tigecycline is not extensively metabolized. *In vitro* studies with tigecycline using human liver microsomes, liver slices, and hepatocytes led to the formation of only trace amounts of metabolites, glucuronide, an N-acetyl metabolite, and a tigecycline epimer were also present.

Elimination

The recovery of total radioactivity in feces and urine following administration of ^{14}C-tigecycline indicates that the dose is eliminated by biliary/fecal excretion, and is excreted in urine. Overall, the primary route of elimination for tigecycline is biliary excretion of unchanged tigecycline. Glucuronidation and renal excretion of unchanged tigecycline are secondary routes.

Tigecycline is a substrate of P-gp based on an *in vitro* study using a cell line over expressing P-gp. The potential contribution of P-gp-mediated transport to the *in vivo* disposition of tigecycline is not known.

Special Populations

Hepatic insufficiency

No dosage adjustment is warranted in patients with mild to moderate hepatic impairment (Child Pugh A and Child Pugh B). However, in patients with severe hepatic impairment (Child Pugh C), the dose of tigecycline should be reduced to 100 mg followed by 25 mg every 12 hours. Patients with severe hepatic impairment (Child Pugh C) should be treated with caution and monitored for treatment response (see section 4.2).

Renal insufficiency

No dosage adjustment of tigecycline is necessary in patients with renal impairment or in patients undergoing hemodialysis (see section 4.2).

Elderly

No dosage adjustment is necessary based on age.

Children

The pharmacokinetics of tigecycline in patients less than 18 years of age have not been established.

Gender

No dosage adjustment is necessary based on gender.

Race

No dosage adjustment is necessary based on race.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

Compatible intravenous solutions include 0.9% Saline solution, 5% Dextrose and Lactate Ringer's Injection.

Tigecycline is compatible with the following drugs or diluents when used with either 0.9%

Saline solution or 5% Dextrose or Lactate Ringer's Injection and administered simultaneously through the same line: amikacin, dobutamine, dopamine HCl, gentamicin, haloperidol, Lactate Ringer's, lidocaine HCl, metoclopramide, morphine, norepinephrine, piperacillin / tazobactam (EDTA formulation), potassium chloride, propofol, ranitidine HCl, theophylline, and tobramycin.

The following drugs should not be administered simultaneously through the same line as tigecycline:

amphotericin B, amphotericin B lipid complex, diazepam, esomeprazole and omeprazole.

6.2 Shelf life

Observe "Expiry date" (month/year) imprinted on outer carton.

6.3 Special precautions for storage

Unopened vial: Do not store above 30°C.

Once reconstituted, the product should be administered immediately.

Reconstituted solution must be transferred and further diluted for IV infusion.

Single use vial. Discard unused portion.

6.4 Nature and contents of container

Tigecycline for injection is supplied in a single-dose 5 ml glass vial containing 50 mg lyophilized powder for reconstitution.

Supplied 1 vial/box and 10 vials/box.

6.5 Instructions for use and handling

The lyophilized powder should be reconstituted with 5.3 ml of 0.9% Saline solution or 5% Dextrose or Lactate Ringer's Injection, to achieve a concentration of 10 mg/ml of tigecycline. The vial should be gently swirled until the drug dissolves. Withdrawal 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 into a 100 ml IV bag (Note: The vial contains a 6% overage. Thus, 5 ml of reconstituted solution is equivalent to 50 mg of the drug). The reconstituted solution should be orange to orange red in colour if not, the solution should be discarded. Parenteral drug products should be inspected visually for particulate matter and discoloration (e.g., green or black) prior to administration whenever solution and container permit. Once reconstituted, tigecycline should be used immediately.

Tigecycline may be administered intravenously through a dedicated line or through a Y-site. If the same intravenous line is used for sequential infusion of several drugs, the line should be flushed before and after infusion of tigecycline with either 0.9% Saline solution or 5% Dextrose or Lactate Ringer's Injection. Injection should be made with an infusion solution compatible with tigecycline and with any other drug(s) administrated via this common line (see section 6.1).

6.6 Manufacturer
Gland Pharma Limited,
Survey No 143-148, 150&151
Near Gandimaisamma Cross Roads
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6.7 Product Registration Holder
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6.8 Date of revision
25/07/2023

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