# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

S4

**TIZEG powder for solution for infusion**

**Tigecycline 50 mg/vial**

**Sugar free**

**Read all of this leaflet carefully before you are administered Tizeg**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or nurse.

**What is in this leaflet**

1. What **TIZEG** is and what it is used for
2. What you need to know before you receive **TIZEG**
3. How **TIZEG** is given
4. Possible side effects
5. How to store **TIZEG**
6. Contents of the pack and other information

## 1. What TIZEG is and what it is used for

**TIZEG** contains the active ingredient tigecycline. Tigecycline is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

Your doctor has prescribed **TIZEG** to treat one of the following types of serious infections that you have:

- Complicated infection of the skin and soft tissues (the tissue below the skin).
- Complicated infection in the abdomen.

## 2. What you need to know before TIZEG is given to you TIZEG should not be given to you:

- If you are hypersensitive (allergic) to tigecycline or any of the other ingredients in **TIZEG** (listed in **section 6**);
- If you are pregnant or breast-feeding.

### Warnings and precautions

Tell your doctor or health care provider before receiving **TIZEG:**

- If you have poor or slow wound healing.
- If you have, or previously had liver problems. Depending on the condition of your liver, your doctor may reduce the dose to avoid potential side effects.
- If you have or previously had any side effects due to antibiotics belonging to the tetracycline class (e.g., skin sensitization to sun light, staining on developing teeth, pancreas inflammation, and alteration of certain laboratory values aimed at measuring how well your blood clots).
- If you suffer from a bleeding disorder or are in treatment with anticoagulant drugs, as this medicine can interfere with blood coagulation
- If you have blockage of the bile ducts (cholestasis).
- If you are suffering from diarrhoea before you are given **TIZEG**. If you develop diarrhoea during or after your treatment, tell your doctor at once. Do not take any diarrhoea medicine without first checking with your doctor.

During treatment with tigecycline:

- Tell your doctor immediately if you develop symptoms of an allergic reaction.
- Tell your doctor immediately if you develop severe abdominal pain, nausea, and vomiting. These may be symptoms of acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting).

- In certain serious infections, your doctor may consider to use tigecycline in combination with other antibiotics.
- Your doctor will monitor you closely for the development of any other bacterial infections. If you develop another bacterial infection, your doctor may prescribe a different antibiotic specific for the type of infection present.
- Although antibiotics including tigecycline fight certain bacteria, other bacteria and fungi may continue to grow. This is called overgrowth. Your doctor will monitor you closely for any potential infections and treat you if necessary.

**Children and adolescents**

The safety and effectiveness of **TIZEG** in patients under 18 years of age is not established. Therefore, **TIZEG** should not be used in patients under 18 years of age.

If you are not sure if any of the above applies to you, talk to your doctor or health care provider before receiving **TIZEG**.

**Other medicines and TIZEG**

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines).

- Tigecycline may prolong certain tests that measure how well your blood is clotting. It is important that you tell your doctor if you are taking medicines to avoid an excess of blood clotting (named anticoagulants). If this were the case, your doctor will monitor you closely.
- Tigecycline may interfere with the contraceptive pill (birth control pill). Talk to your doctor about the need for an additional method of contraception while receiving tigecycline.

- Tigecycline may increase the effect of medicines used to suppress the immune system (such as tacrolimus or cyclosporine).It is important that you tell your doctor if you are taking these medicines so you can be closely monitored.
- Ketoconazole (medicine used to treat fungal infections)
- Rifampicin (medicine used to treat bacterial infections)

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor for advice before receiving this medicine.
Tigecycline may cause foetal harm. **TIZEG** should not be used during pregnancy.
It is not known if tigecycline passes into breast milk in humans. Ask your doctor for advice before breast-feeding your baby.

**Driving and using machines**

Tigecycline may cause side effects such as dizziness. This may impair your ability to drive or operate machinery.

This medicinal product contains 71.77 mg sodium per 5 mL of reconstituted solution for infusion, equivalent to 3,6% of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

**3. How TIZEG is given**

Do not share medicines prescribed for you with any other person. You will not be expected to give yourself **TIZEG**. It will be given to you by a person who is qualified to do so. The healthcare professional will administer your correct dose.

The usual dose is 100 mg given initially, followed by 50 mg every12 hours. **TIZEG** is administered as an intravenous (IV) infusion (directly into your blood stream) over approximately 30 to 60 minutes every 12 hours.
The recommended duration of treatment with **TIZEG** is 5-14 days. Your doctor will tell you how long your treatment with **TIZEG** will last.

**If you receive more TIZEG than you should**

Since a health care provider will administer **TIZEG**, he / she will control the dosage.
However, in the event of overdosage, your doctor will manage the overdosage.

**If you miss a dose of TIZEG**

Since a health care provider will administer **TIZEG**, it is unlikely that the dose will be missed.

If you have any further questions on the use of this product, ask your doctor or healthcare professional.

## 4. Possible side effects

**TIZEG** can have side effects.
Not all side effects reported for **TIZEG** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **TIZEG**, please consult your healthcare provider for advice.

If any of the following happens, stop using **TIZEG** and tell your or their doctor immediately or go to the casualty department at your or their nearest hospital:

- Anaphylaxis/anaphylactoid reaction (sudden life threatening allergic reaction. Symptoms include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing).
- Stevens Johnson syndrome (severe blistering or peeling of the skin; bleeding in the lips, eyes, mouth, nose and genitals; swelling around the eyes, lips and face, rashes caused by exposure to sunlight).
- Sepsis (severe infection in the body and blood stream)/septic shock (serious medical condition which can lead to multiple organ failure and death as a result of sepsis).

These are all very serious side effects. If they occur, you have had a serious reaction to T**IZEG**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Acute pancreatitis (inflammation of pancreas. Symptoms may include severe upper stomach pain, often with nausea and vomiting);
- Liver failure (symptoms may include yellowing of skin and eyeballs, nausea, vomiting, sleepiness, confusion, abdominal swelling);
- Jaundice (symptoms include yellowing of skin or eyes, fever, chills, flu-like symptoms), liver injury.

**Tell your doctor if you notice any of the following:**

**Frequent side effects:**

- Pneumonia (infection of lungs. Symptoms may include chest pain when you breathe or cough, cough which may produce phlegm, shortness of breath, fatigue, fever, sweating and chills)
- Abscess (collection of pus)

- Infections
- Laboratory measurements of decreased ability to form blood clots
- Hypoglycaemia (low blood sugar. Symptoms may include shakiness, anxiety, sweating, pale skin, dizziness, sleepiness, confusion)
- Hypoproteinaemia (low protein levels in the blood. Symptoms may include swelling in the lungs, face and other parts of body from fluid build-up, loss of muscle mass, lack of growth in children, infections, tiredness, cracked and pitted nails)
- Dizziness
- Phlebitis (vein irritations from the injection, including pain, inflammation, swelling and clotting)
- Nausea (feeling sick), vomiting (being sick), diarrhea (loose stools), abdominal pain, dyspepsia (indigestion), anorexia (loss of appetite)
- Increased liver enzymes, hyperbilirubinaemia (excess of bile pigment in blood, causing yellow discoloration of eyes and skin, called jaundice)
- Pruritus (itching), rash
- Impaired healing, headache
- Increase in amylase, which is an enzyme found in the salivary glands and pancreas, increased blood urea nitrogen (BUN).
- Bilirubinaemia (The presence of excess bilirubin in the blood)

**Less frequent side effects:**

- Thrombocytopenia (low blood platelet count. Symptoms include bleeding or bruising more easily than normal),
- Increased international normalised ratio (INR), hypofibrinogenaemia (low fibrinogen (protein involved in blood clotting) levels in blood. Symptoms may include heavy menstrual bleeding, muscle ache, upset stomach, vomit that is black and syrupy or bright red, red or black coloured stool, tight and shiny appearance of skin)

- Thrombophlebitis (swelling and redness along a vein related to blood clot which is extremely tender when touched)
- Injection site inflammation, injection site pain, injection site oedema (swelling and irritation at the site of injection), injection site phlebitis (pain at site of injection)
- Injection site reaction (pain, redness, inflammation)
- Hypoproteinaemia (low levels of protein in the blood)

**Frequency not known:**

- Hepatic cholestasis (a condition that impairs the release of a digestive fluid called bile from liver cells).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or healthcare professional.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **TIZEG**.

## 5. How to store TIZEG

Before reconstitution:

Stored at temperatures not exceeding 25 °C. Keep the vial in the outer carton to protect from light.

Reconstituted solution:

Once reconstituted in the I.V. bag, **TIZEG** may be stored at room temperature (not to exceed 25 °C) for up to 24 hours (up to 6 hours in the vial and the remaining time in the IV bag). Alternatively, **TIZEG** mixed with 0,9 % Sodium Chloride Injection, USP, 5 % Dextrose Injection, USP, or Lactated Ringer's Injection USP may be stored refrigerated at 2 °C to 8 °C for up to 48 hours following immediate transfer of the reconstituted solution into the IV bag. If

the storage conditions exceed 25 °C after reconstitution, **TIZEG** should be used immediately.

Keep out of the reach of children.

## 6. Contents of the pack and other information

### What TIZEG contains

The active substance is tigecycline.

**The other ingredients are:** sulphobutyl ether betacyclodextrin sodium, hydrochloric acid, water for injection.

### What TIZEG looks like and contents of the pack

**TIZEG** is packed in a 10 mL clear glass vial stoppered with slotted grey bromobutyl rubber stopper and sealed with an orange aluminium flip-off seal. One such vial will be packed in a plastic tray and such one tray packed in a monocarton along with leaflet. Ten such labelled vials will be packed in a carton with separator along with a leaflet.

### Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd.,

a Sun Pharma company

14 Lautre Road, Stormill Ext 1,

Roodepoort, 1724,

South Africa

### This leaflet was last revised in:

31 January 2025

### Registration numbers

56/20.1.1/0531

**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS**

S4

**TIZEG poeier vir oplossing vir infusie**

**Tigesiklien 50 mg/flessie**

**Suikervry**

**Lees hierdie hele inligtingstuk noukeurig deur voordat TIZEG aan jou toegedien word**

- Hou hierdie inligtingstuk. Jy mag dit moontlik weer wil lees.
- Vra asseblief jou dokter of verpleegkundige as jy verdere vrae het.

**Wat is in hierdie inligtingstuk**

1. Wat **TIZEG** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat **TIZEG** aan jou toegedien word
3. Hoe **TIZEG** toegedien word
4. Moontlike newe-effekte
5. Hoe om **TIZEG** te bewaar
6. Inhoud van die verpakking en ander inligting

## 1. Wat TIZEG is en waarvoor dit gebruik word

**TIZEG** bevat die aktiewe bestanddeel tigesiklien. Tigesiklien is ‘n antibiotikum van die glisielsikliengroep. Dit stop die groei van bakterieë wat infeksies veroorsaak.

Jou dokter het **TIZEG** voorgeskryf vir die behandeling van een van die volgende tipes ernstige infeksies wat jy het:

- Gekompliseerde infeksie van die vel en sagte weefsel (die weefsel onder die vel).
- Gekompliseerde infeksie in die abdomen.

## 2. Wat jy moet weet voordat TIZEG aan jou toegedien word

**PASIËNTINLIGTINGSTUK**

**TIZEG moet nie aan jou toegedien word nie:**

- as jy hipersensitief (allergies) is vir tigesiklien of enige van die ander bestanddele in **TIZEG** (gelys in **afdeling 6**);
- as jy swanger is of borsvoed.

**Waarskuwings en voorsorgmaatreëls**

Voordat **TIZEG** aan jou toegedien word, sê vir jou dokter of gesondheidsorgvoorsiener:

- as jy swak of stadige wondgenesing het;
- as jy lewerprobleme het, of voorheen gehad het. Afhangend van die toestand van jou lewer, kan jou dokter besluit om die dosis te verlaag om moontlike newe-effekte te vermy;
- as jy enige newe-effekte het, of voorheen gehad het, as gevolg van antibiotika wat aan die tetrasiklienklas behoort (bv. velsensitisasie vir sonlig, verkleuring op ontwikkelende tande, inflammasie van die pankreas, en verandering van sekere laboratoriumwaardes gemik op die bepaling van hoe goed jou bloed stol);
- as jy aan ‘n bloedingversteuring ly of op behandeling is met antistol-geneesmiddels, aangesien hierdie middel kan inmeng met bloedstolling.
- as jy ‘n blokkasie van die galbuise het (cholestase).
- as jy aan diarree ly voordat **TIZEG** aan jou toegedien word. Lig jou dokter ook dadelik in as jy diarree ontwikkel tydens of ná jou behandeling. Moenie enige medisyne vir diarree gebruik voordat jy dit eers met jou dokter uitgeklaar het nie.

Tydens behandeling met tigesiklien:

- Lig jou dokter onmiddellik in as jy simptome van ‘n allergiese reaksie ontwikkel.
- Lig jou dokter onmiddellik in as jy ernstige maagpyn, naarheid en diarree ontwikkel. Dit kan simptome van akute pankreatitis wees (ontsteekte pankreas wat kan lei tot ernstige maagpyn, naarheid en braking).
- In sekere ernstige infeksies, kan jou dokter oorweeg om tigesiklien in kombinasie met ander antibiotika te gebruik.
- Jou dokter sal jou noukeurig monitor vir die ontwikkelling van enige ander bakteriële infeksies. As jy ‘n ander bakteriële infeksie ontwikkel, kan jou dokter ‘n ander antibiotikum voorskryf spesifiek vir die tipe infeksie teenwoordig.

**PASIËNTINLIGTINGSTUK**

- Alhoewel antibiotika, insluitend tigesiklien, sekere bakterieë beveg, kan ander bakterieë en fungi aanhou om te groei. Dit word oorgroeiing genoem. Jou dokter sal jou noukeurig monitor vir enige potensiële infeksies en jou daarvoor behandel indien nodig.

**Kinders en adolessente**

Die veiligheid en doeltreffendheid van **TIZEG** in pasiënte onder die ouderdom van 18-jaar is nie vasgestel nie. Daarom moet **TIZEG** nie aan pasiënte onder die ouderdom van 18-jaar toegedien word nie.

As jy nie seker is of enige van die bogenoemde op jou van toepassing is nie, moet jy jou dokter of gesondheidsorgvoorsiener raadpleeg voordat **TIZEG** aan jou toegedien word.

**Ander medisyne enTIZEG**

Lig jou gesondheidsorgvoorsiener altyd in as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in).

- Tigesiklien kan sekere toetse wat bepaal hoe goed jou bloed stol, verleng. Dit is belangrik dat jy jou dokter inlig as jy medisyne gebruik wat verhoed dat jou bloed oormatig stol (wat antistolmiddels genoem word). As dit die geval is, sal jou dokter jou noukeurig monitor.
- Tigesiklien kan inmeng met die voorbehoedpil (geboortebeperkingspil). Praat met jou dokter oor die behoefte aan ‘n bykomende metode van voorbehoeding terwyl jy met tigesiklien behandel word.
- Tigesiklien kan die effek van medisyne wat gebruik word om die immuunstelsel te onderdruk (soos takrolimus of siklosporien) verhoog. Dit is belangrik om jou dokter in te lig as jy hierdie medisyne gebruik, sodat jy noukeurig gemonitor kan word.
- Ketokonasool (medisyne wat gebruik word om fungusinfeksies te behandel)
- Rifampisien (medisyne wat gebruik word om bakteriële infeksies te behandel)

**Swangerskap en borsvoeding**

As jy swanger is of borsvoed, vermoed dat jy swanger mag wees of beplan om ‘n baba te hê, moet jy asseblief jou dokter raadpleeg vir advies voordat hierdie medisyne aan jou toegedien word.

Tigesiklien kan fetale skade veroorsaak. **TIZEG** moet nie tydens swangerskap gebruik word nie.

Dit is nie bekend of tigesiklien in die borsmelk van mense oorgedra word nie. Raadpleeg jou dokter vir advies voordat jy jou baba borsvoed.

**PASIËNTINLIGTINGSTUK**

**Bestuur van voertuie en gebruik van masjinerie**

Tigesiklien kan newe-effekte, soos duiseligheid, veroorsaak. Dit kan jou vermoë benadeel om ‘n voertuig te bestuur of masjinerie te hanteer.

Hierdie medisinale produk bevat 71,77 mg natrium per 5 mL van hersaamgestelde oplossing vir infusie, gelykstaande aan 3,6 % van die WGO se aanbevole maksimum daaglikse inname van 2 g natrium vir ‘n volwassene. Dit moet in ag geneem word by pasiënte op ‘n gekontroleerde natriumdieet.

## 3. Hoe TIZEG toegedien word

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Daar sal nie van jou verwag word om **TIZEG** aan jouself toe te dien nie. ‘n Persoon wat opgelei is om dit te doen, sal die toediening behartig. Die gesondheidsorgvoorsiener sal die korrekte dosis aan jou toedien.

Die dosis is gewoonlik 100 mg wat aanvanklik toegedien word, gevolg deur 50 mg elke 12 uur. **TIZEG** word toegedien as ‘n intraveneuse (IV) infusie (direk binne-in jou bloedstroom) oor ‘n tydperk van ongeveer 30 tot 60 minute elke 12 uur.

Die aanbevole duur van behandeling met **TIZEG** is 5 tot 14 dae. Jou dokter sal jou inlig oor hoe lank jou behandeling met **TIZEG** sal duur.

**As jy meer TIZEG ontvang as wat jy behoort te ontvang**

Die gesondheidsorgvoorsiener wat **TIZEG** sal toedien, sal die dosis kontroleer. In die geval van oordosering, sal jou dokter egter die oordosering bestuur.

**As jy ‘n dosis van TIZEG oorslaan**

Aangesien die gesondheidsorgvoorsiener **TIZEG** sal toedien, is dit onwaarskynlik dat die toediening van die dosis oorgeslaan sal word.

Vra jou dokter of gesondheidsorgvoorsiener as jy enige verdere vrae oor die gebruik van hierdie produk het.

## 4. Moontlike newe-effekte

**TIZEG** kan newe-effekte hê.

**PASIËNTINLIGTINGSTUK**

Nie alle newe-effekte wat vir **TIZEG** aangemeld word, is in hierdie inligtingstuk ingesluit nie. Indien jou algemene gesondheid sou verswak of as jy enige ongunstige effekte ervaar terwyl jy **TIZEG** ontvang, moet jy asseblief jou gesondheidsorgvoorsiener raadpleeg vir advies.

**Indien enige van die volgende gebeur, staak die gebruik van TIZEG en lig jou of hulle dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou of hulle naaste hospitaal:**

- Anafilaktiese/anafilaktoïede reaksie (skielike lewensbedreigende allergiese reaksie. Simptome sluit uitslag, gejeuk of galbulte op die vel, swelling van die gesig, lippe, tong of ander dele van die liggaam, kortasemigheid, hyging of moeilike asemhaling in).
- Stevens Johnson se sindroom (ernstige blasievorming of afskilfering van die vel; bloeding van die lippe, oë, mond, neus en geslagsdele; swelling rondom die oë, lippe en gesig, uitslag veroorsaak deur blootstelling aan sonlig).
- Sepsis (ernstige infeksie in die liggaam en bloedstroom)/septiese skok (ernstige mediese toestand wat kan lei tot veelvuldige orgaanversaking en sterfte weens die sepsis)

Hierdie is almal baie ernstige newe-effekte. As dit voorkom, het jy moontlik ‘n ernstige reaksie teen **TIZEG** gehad het**.** Jy mag dringende mediese aandag of hospitalisasie benodig.

**Lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:**

- Akute pankreatitis (inflammasie van die pankreas. Simptome kan ernstige pyn in die bodeel van die maag insluit, dikwels saam met naarheid en braking);
- Lewerversaking (simptome kan vergeling van die vel en oogbolle, naarheid, braking, slaperigheid, verwarring, abdominale swelling insluit);
- Geelsug (simptome sluit vergeling van die vel en oë, koors, koudheid, griepagtige simptome in), lewerbesering

**Lig jou dokter in as jy enige van die volgende opmerk:**

**Gereelde newe-effekte:**

- Pneumonie (infeksie van die longe. Simptome kan borskaspyn insluit wanneer jy asemhaal of hoes, hoes wat slym kan produseer, kortasemigheid, moegheid, koors, sweet en koudheid)
- Absesse (versameling van etter)
- Infeksies
- Laboratoriumbepalings van verlaagde vermoë om bloedklonte te vorm

**PASIËNTINLIGTINGSTUK**

- Hipoglisemie (lae bloedsuiker. Simptome kan bewerigheid, angstigheid, sweet, bleek vel, duiseligheid, slaperigheid of verwarring insluit)
- Hipoproteïenemie (lae proteïenvlakke in die bloed. Simptome kan swelling in die longe, gesig of ander dele van die liggaam insluit as gevolg van die opbou van vloeistof, verlies aan spiermassa, gebrek aan groei in kinders, infeksies,moegheid of gebreekte naels en duikies of groefies op naels insluit)
- Duiseligheid
- Flebitis (irritasies van die aar as gevolg van die inspuiting, insluitend pyn, inflammasie, swelling en klontvorming)
- Naarheid (voel mislik), braking (gooi op), diarree (los stoelgange), abdominale pyn, dispepsie (slegste spysvertering), anoreksie (verlies aan aptyt)
- Verhoogde lewerensieme, hiperbilirubinemie (oormaat van galpigment in die bloed, wat geel verkleuring van oë en vel veroorsaak, wat geelsug genoem word)
- Pruritus (gejeuk), uitslag
- Vertraagde genesing, hoofpyn
- Verhoging in amilase, wat ‘n ensiem is wat in die speekselkliere en pankreas gevind word, verhoogde bloedureumstikstof (BUN).
- Bilirubinemie (die teenwoordigheid van oormatige bilirubien in die bloed)

**Minder gereelde newe-effekte:**

- Trombositopenie (lae bloedplaatjie-telling. Simptome sluit in bloeding of makliker kneusing as normaalweg),
- Verhoogde Internasionale Genormaliseerde Ratio (INR), hipofibrinogenemie, lae fibrinogen-(proteïen betrokke by bloedstolling) vlakke in die bloed. Simptome kan swaar menstruele bloeding, spierpyn, ontstelde maag, braaksel wat swart en stroperig of helder-rooi is, rooi of swart gekleurde stoelgang, stywe en blink voorkoms van die vel insluit.)
- Tromboflebitis (swelling en rooiheid langs ‘n aar verwant aan ‘n bloedklont wat uiters teer is wanneer aangeraak word)
- Inflammasie van die inspuitplek, pyn by die inspuitplek, edeem by die inspuitplek (swelling en irritasie by die inspuitplek), inspuitplek flebitis (pyn by die inspuitplek)
- Inspuitplekreaksie (pyn, rooiheid, inflammasie)
- Hipoproteïenemie (lae vlakke van proteïen in die bloed)

**Voorkoms onbekend:**

**PASIËNTINLIGTINGSTUK**

- Hepatiese cholestase (‘n toestand wat die vrystelling van ‘n verteringsvloeistof vanaf lewerselle, wat gal genoem word, inkort)

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk gemeld is nie, moet jy asseblief jou dokter of gesondheidsorgvoorsiener inlig.

**Aanmelding van newe-effekte**

Indien jy newe-effekte ondervind, bespreek dit met jou dokter if apteker. Jy kan ook newe-effekte aan SAHPRA rapporteur via die Med Safety APP (Medsafety X SAHPRA) en e-verslaggewing platform (who-umc.org) gevind op SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om inligting oor die veiligheid van **TIZEG** te verskaf.

## 5. Hoe om TIZEG te bewaar

Vóór hersamestelling:

Bewaar by temperature wat nie 25 °C oorskry nie.

Hou die flessie in die buitenste karton om dit teen lig te beskerm.

Hersaamgestelde oplossing:

Sodra dit in die IV-sakkie hersaamgestel is, kan **TIZEG** teen kamertemperatuur (moet nie 25 °C oorskry nie) vir tot 24 uur (tot 6 uur in die flessie en die res van die tyd in die IV-sakkie) bewaar word. Anders kan **TIZEG**, wanneer gemeng met 0.9 % Natriumchloried-inspuiting, USP, 5 % Dektrose-inspuiting, USP, of Ringerslaktaat-inspuiting USP, in ‘n yskas teen 2 °C tot 8 °C vir tot 48 uur ná onmiddellike oordrag van die hersaamgestelde oplossing binne-in die IV-sakkie bewaar word.

Indien die bewaringstoestande ná hersamestelling 25 °C oorskry, moet **TIZEG** dadelik gebruik word.

**Hou buite die bereik van kinders**.

## 6. Inhoud van die verpakking en ander inligting

**Wat TIZEG bevat**

Die aktiewe bestanddeel is tigesiklien.

**Die ander bestanddele is:** natriumsulfobutieleter-betasiklodekstrien, soutsuur, water vir inspuiting.

**Hoe TIZEG lyk en inhoud van die verpakking**

## PASIËNTINLIGTINGSTUK

**TIZEG** word verpak in ‘n 10 mL helder glasflessie toegemaak met ‘n grys bromobutiel-rubberprop en verseël met ‘n oranje aftrekbare aluminiumseël. Een so ‘n flessie word in ‘n plastiekhouer verpak en een plastiekhouer word afsonderlik saam met die inligtingstuk in ‘n kartonhouer verpak.

**Houer van die Registrasiesertifikaat**
Ranbaxy Pharmaceuticals (Pty) Ltd.
‘n Sun Pharma maatskappy
Lautreweg 14, Stormill Uitbreiding 1,
Roodepoort, 1724,
Suid-Afrika.

**Hierdie inligtingstuk is laas hersien in:**
31 Januarie 2025
**Registrasienommer**