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

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

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