Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: TACYL
Registration number: TACYL: 53/17.1/0630	Dosage form & strength: Each vial contains 50 mg tigecycline sterile powder for solution for intravenous infusion

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TACYL, 50 mg, powder for solution for intravenous infusion

Tigecycline

TACYL is sugar free

Read all of this leaflet carefully before you are given TACYL.

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

WHAT IS IN THIS LEAFLET:

1. WHAT TACYL IS AND WHAT IT IS USED FOR:

TACYL is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

Your doctor has prescribed TACYL because you has one of the following types of serious infections:

- Complicated infection of the skin and soft tissues (the tissue below the skin), excluding diabetic foot

infections

- Complicated infection in the abdomen

TACYL is only used when your doctor thinks other antibiotics are not suitable.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TACYL:

TACYL should not be administered to you:

- If you are hypersensitive (allergic) to tigecycline or to any other ingredients of TACYL.
- If you are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to tigecycline as contained in TACYL.
- If you are pregnant or breastfeeding

Warnings and precautions:

Taking special care with TACYL:

Tell your doctor or healthcare provider before being given the injection:

- If you experience impaired healing of surgical wounds, your doctor may consider using TACYL in combination with other antibiotics in certain serious infections
- If you develop another bacterial infection, your doctor may prescribe a different antibiotic specific for the type of infection present. Your doctor will monitor you closely for the development of any other bacterial infections
- If you develop symptoms of an allergic reaction, tell you doctor immediately
- 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 are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to TACYL

- If you develop severe abdominal pain, nausea, and vomiting, tell you doctor immediately. These may be symptoms of acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
- If you have or previously had any side effects due to antibiotics belonging to the tetracycline class (e.g., skin sensitisation to sun light, staining on developing teeth and alteration of certain laboratory values aimed at measuring how well your blood clots)
- If you have underlying diseases such as diabetes, peripheral vascular disease and HIV
- If you have blockage of the bile ducts (cholestasis)
- If you are suffering from diarrhoea before you are given TACYL. 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
- Although antibiotics including TACYL 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:

TACYL should not be used in children.

Other medicines and TACYL:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

TACYL 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.

TACYL may interfere with the contraceptive pill (birth control pill). Talk to your doctor about the need for an additional method of contraception while receiving TACYL.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving TACYL.

TACYL may cause foetal harm.

It is not known if TACYL passes into breast milk in humans.

You should not receive TACYL if you are pregnant or breastfeeding your baby.

Driving and using machines:

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

It is not always possible to predict to what extent TACYL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving a vehicle or using machines until they are aware of the measure to which TACYL affects them.

3. How to use TACYL:

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with TACYL will last.

If you have the impression that the effect of TACYL is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself TACYL. It will be given to you by a person who is qualified to do so.

The recommended dose in adults is 100 mg given initially, followed by 50 mg every 12 hours. This dose is given intravenously (directly into your blood stream) over a period of 30 to 60 minutes.

TACYL should not be given to children under 18 years of age.

A course of treatment usually lasts for 5 to 14 days. Your doctor will decide how long you should be treated.

If you use more TACYL than you should:

Since a healthcare provider will administer TACYL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TACYL

Since a healthcare provider will administer TACYL, it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS:

TACYL can have side effects.

Not all side effects reported for TACYL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving TACYL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop receiving TACYL and tell your doctor immediately and go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to TACYL. 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:

Frequent side effects:

- 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)
- pneumonia (lung infection)

Less frequent side effects:

- acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
- jaundice (yellow coloration of the skin), inflammation of the liver.

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abscess (collection of pus), infections
- decreased ability to form blood clots
- low blood sugar
- low protein levels in the blood
- dizziness
- vein irritations from the injection, including pain, inflammation, swelling and clotting

- stomach pain, dyspepsia (stomach ache and indigestion), anorexia (loss of appetite)
- increases in liver enzymes, hyperbilirubinaemia (excess of bile pigment in the blood)
- poor or slow wound healing
- headache
- injection site reaction (pain, redness, inflammation)
- increase in amylase, which is an enzyme found in the salivary glands and pancreas, increased blood urea nitrogen (BUN).

Less frequent side effects:

- low platelet levels in the blood (which may lead to an increased bleeding tendency and bruising/haematoma)
- inflammation of the wall of a vein with associated thrombosis
- pain, inflammation or swelling at the injection site

Side effects with unknown frequency:

- low fibrinogen levels in the blood (a protein involved in blood clotting)
- liver failure
- skin rash, which may lead to severe blistering and peeling of the skin (Stevens-Johnson syndrome).

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **'6.04 Adverse Drug Reaction Reporting Form'**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TACYL.

5. HOW TO STORE TACYL:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Protect from light and moisture.

Keep the container tightly closed and keep in the carton until required for use.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Storage after preparation:

Chemical and physical in-use stability has been demonstrated for TACYL mixed with 0,9 % Sodium chloride injection or Dextrose 5 %. The product may be stored refrigerated at 2 ºC to 8 ºC for up to 48 hours following immediate transfer of the reconstituted solution into the intravenous bag.

From a microbiological point of view, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

The TACYL solution should be yellow to orange in colour after dissolving; if it is not, the solution should be discarded.

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What TACYL contains:

The active ingredient is tigecycline. Each vial contains 50 mg of tigecycline.

The other ingredient is L-arginine.

What TACYL looks like and contents of the pack:

TACYL is a lyophilised orange to orange-red cake or powder before it is diluted.

TACYL is packaged in a 5 ml Type 1 clear glass vials fitted with grey butyl rubber stoppers and aluminium flip-off seal with a top orange plastic cap, packed inside a cardboard carton.

TACYL is supplied in a cardboard unit carton as a pack size of 10 vials.

Holder of Certificate of Registration:

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