PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TYGACIL 50 mg Sterile powder for intravenous infusion

Tigecycline

Contains sugar (lactose monohydrate)

Each 5 mL vial contains 106 mg lactose monohydrate

Read all of this leaflet carefully before you are given TYGACIL Sterile powder for intravenous infusion

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TYGACIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What TYGACIL is and what it is used for

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

TYGACIL is used in:

- Infection of the skin excluding diabetic foot infections
- Infection in the abdomen

2. What you need to know before you are given TYGACIL

You should not be given TYGACIL:

- if you are hypersensitive (allergic) to tigecycline or any of the other ingredients of TYGACIL (listed in section 6)
- if you are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to tigecycline
- if you are pregnant, think you might be pregnant, or are breastfeeding
- if you have pneumonia that developed during your stay in hospital

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you develop symptoms of an allergic reaction
- if you develop severe abdominal pain, nausea, and vomiting. These may be symptoms of acute pancreatitis
- if you are suffering from diarrhoea before you are given TYGACIL. 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
- 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, pancreas inflammation, and alteration of certain laboratory values aimed at measuring how well your blood clots)
- in certain serious infections, your doctor may consider using TYGACIL in combination with other antibiotics
- if you suffer from a bleeding disorder or are on treatment with anticoagulant medicines, as TYGACIL can interfere with blood coagulation (see Other medicines and TYGACIL)
- if you are taking the contraceptive pill, as you may need an additional method of contraception while

receiving TYGACIL (see Other medicines and TYGACIL)

- 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
- while antibiotics including TYGACIL fight certain bacteria, other bacteria and fungi may continue to grow. This is called overgrowth. Your doctor will monitor you for any potential infections and treat you if necessary
- TYGACIL is not recommended for use in children or adolescents (under 18 years of age)

Other medicines and TYGACIL

Always tell your health care provider if you are taking any other medicine (This includes all complimentary or traditional medicines.)

TYGACIL 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. If this is the case, your doctor will monitor you closely.

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

Other medicines may interfere with TYGACIL. Examples of these are ketoconazole (used to treat fungal infections), ciclosporin (an immunosuppressant used during transplant surgery), tacrolimus (an immunosuppressant used following organ transplant) and rifampicin (used to treat tuberculosis). Please consult your doctor if you are taking any of these medicines.

Pregnancy and breastfeeding

If you are pregnant, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given TYGACIL.

TYGACIL may cause foetal harm.

It is not known if TYGACIL passes into breast milk in humans. Because many medicines are excreted in human milk, ask your doctor for advice before breastfeeding your baby.

Driving and using machines

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

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

TYGACIL contains sodium

TYGACIL contains less than 1 mmol sodium (23 mg) per 5 mL of suspension, that is to say essentially 'sodium-free'.

3. How to receive TYGACIL

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

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

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

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

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

pharmacist.

If you receive more TYGACIL than you should

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

If you forget to use TYGACIL

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

4. Possible side effects

TYGACIL can have side effects.

Not all side effects reported for TYGACIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TYGACIL, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- nausea
- vomiting
- diarrhoea
- abscess (collection of pus)
- infections
- laboratory measurements of decreased ability to form blood clots
- low platelet levels in the blood (which may lead to an increased bleeding tendency and bruising)
- dizziness
- vein irritations from the injection, including pain, inflammation, swelling and clotting
- pneumonia
- abdominal pain

- dyspepsia (stomach-ache and indigestion)
- anorexia (loss of appetite)
- increases in liver enzymes
- hyperbilirubinaemia (excess of bile pigment in the blood)
- low protein levels in the blood
- low blood sugar
- pruritus (itching)
- rash
- headache
- impaired healing
- increase in amylase, which is an enzyme found in the salivary glands and pancreas
- increased blood urea

Less 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)
- acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
- jaundice
- inflammation of the liver
- anaphylaxis/anaphylactoid reactions (that may range from mild to severe, including a sudden, generalised allergic reaction that may lead to a life-threatening shock [e.g., difficulty in breathing, drop of blood pressure, fast pulse])
- liver failure
- severe skin reactions, including Stevens-Johnson Syndrome (a skin rash, which may lead to severe blistering and peeling of the skin)
- low fibrinogen levels in the blood (a protein involved in blood clotting)

Pseudomembranous colitis may occur with most antibiotics including TYGACIL. This consists of severe,

persistent or bloody diarrhoea associated with abdominal pain or fever, which can be a sign of serious bowel inflammation, which may occur during or after your treatment.

TYGACIL belongs to the tetracycline class of antibiotics and may have similar adverse effects. Such effects may include fixed eruption (may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching.

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 or pharmacist. 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 TYGACIL.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store TYGACIL

- Store all medicines out of reach of children.
- TYGACIL will be stored in the hospital in the appropriate conditions [stored at or below 25 °C prior to being made into a solution and at room temperature (not to exceed 25 °C) for up to 24 hours or at 2 °C to 8 °C for up to 48 hours once transferred to the infusion bag].
- If the storage conditions exceed 25 °C after reconstitution, TYGACIL should be used immediately.
- Do not use TYGACIL after the expiry date which is stated on the vial.

Storage after preparation

Once the powder has been made into a solution and diluted ready for use, it should be given to you almost immediately.

6. Contents of the pack and other information

What TYGACIL contains

- The active substance is tigecycline. Each 5 mL vial contains 50 mg tigecycline.
- The other ingredient is lactose monohydrate.

What TYGACIL looks like and contents of the pack

TYGACIL is an orange lyophilised powder or cake.

TYGACIL is packaged in Type I clear glass vials fitted with grey butyl rubber stoppers and snap-off aluminium crimp seals. TYGACIL is supplied in a cardboard unit carton containing 10 vials. Each single-dose, 5 mL glass vial contains 50 mg lyophilised powder for infusion.

Holder of Certificate of Registration

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