

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

TYGIV, 50 mg powder for solution for infusion

Tigecycline

Contains sugar (lactose monohydrate)

Each vial contains 106 mg lactose monohydrate

Read all of this leaflet carefully before you are given TYGIV

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

1. What TYGIV is and what it is used for

TYGIV is an antibiotic of the glycyclcycline group that works by stopping the growth of bacteria that cause infections.

TYGIV is used for the following severe, life-threatening infections:

- complicated skin and soft tissue infections, excluding diabetic foot infections
- complicated abdominal infections.

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

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

You should not be given TYGIV:

- if you are hypersensitive (allergic) to tigecycline or any other ingredient of TYGIV (listed in section 6)
- if you are allergic to tetracycline class of antibiotics (such as minocycline, doxycycline) you may be allergic to TYGIV
- if you are pregnant, think you might be pregnant, or breastfeed your baby

Warnings and precautions

Taking special care with TYGIV

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

- if you have an allergy to some antibiotics as you may have a severe allergic reaction (anaphylaxis) when given TYGIV (see section 4)
- if you have developed pneumonia in hospital, as TYGIV should not be given for hospital-acquired pneumonia or ventilator associated pneumonia
- if you are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to TYGIV
- if you have or previously had any side effects due to antibiotics belonging to the tetracycline class, e.g., skin sensitisation to sunlight (photosensitivity), pancreas inflammation (pancreatitis), pseudotumor cerebri (increased pressure in the skull), alteration of certain laboratory values aimed at measuring how well your blood clots,

increased BUN (blood urea values), uraemia (build-up of toxic substances in blood due to kidney failure), azotaemia (when kidneys fail to filter nitrogen waste from the blood), acidosis (the body fluids become too acidic) and hyperphosphataemia (excessive phosphates in the blood)

- if you currently have or previously experienced staining of developing teeth during treatment with antibiotics from the tetracycline class
- if you experience poor or slow wound healing, as your doctor may consider prescribing a different antibiotic
- if you are suffering from diarrhoea before you are given TYGIV. If you develop diarrhoea during or after your treatment, tell your doctor at once. Do not take any medicine for diarrhoea without first checking with your doctor
- if you suffer from sepsis or septic shock (fast heart rate, fever, sweating, confusion and shortness of breath) after receiving TYGIV alone for severe abdominal infections caused by a tear in the intestines
- 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 blockage of the bile ducts (cholestasis)
- if you develop severe abdominal pain, nausea, and vomiting. These may be symptoms of acute pancreatitis (inflammation of the pancreas)
- if you have underlying diseases such as diabetes, peripheral vascular disease (poor blood flow to the legs), human immunodeficiency virus (HIV), bacteraemia (germs in your blood), diabetic foot infection
- if you suffer from a bleeding disorder or are on treatment with blood thinners, such as warfarin. TYGIV can interfere with blood coagulation (see *Other medicines and TYGIV*)

During treatment with TYGIV:

- Tell your doctor immediately if you develop symptoms of an allergic reaction (see section 4).
- Tell your doctor immediately if you experience severe abdominal pain, nausea, and vomiting. These could be symptoms of acute pancreatitis (an inflamed pancreas, which can lead to severe abdominal pain, nausea, and vomiting).
- In certain serious infections, your doctor may decide to use TYGIV in combination with other antibiotics.
- Your doctor will monitor you closely for the development of any other bacterial infections, including pneumonia (lung infection). If you develop another bacterial infection, your doctor may prescribe a different antibiotic specific for the type of infection present.

While antibiotics including TYGIV 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.

Children

TYGIV should not be used in children or adolescents (under 18 years of age).

Other medicines and TYGIV

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

TYGIV may affect how the following medicines work – tell your doctor if you take any of them:

- Digoxin (a medicine to treat heart problems).

- Blood thinners (warfarin): TYGIV 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 such as warfarin. If this is the case, your doctor will monitor you closely.
- Oral contraceptives: TYGIV may interfere with the contraceptive pill (birth control pill). Talk to your doctor about the need for an additional method of contraception while receiving TYGIV.

Other medicines may affect how TYGIV works:

- Ketoconazole (used to treat fungal infections).
- Rifampicin (used to treat tuberculosis).
- Ciclosporin, tacrolimus (immunosuppressants used in transplant surgery).

Please talk to 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 healthcare provider for advice before being given TYGIV.

TYGIV may cause foetal harm.

It is not known if TYGIV passes into breastmilk in humans.

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

Driving and using machines

TYGIV may cause side effects such as dizziness. Do not drive or operate machinery if you are dizzy.

It is not always possible to predict to what extent TYGIV 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 TYGIV affects them.

TYGIV contains sodium

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

3. How to use TYGIV

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

You will not be expected to give yourself TYGIV. 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.

Your doctor will decide how long you should be treated.

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

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

If you receive more TYGIV than you should

Since a healthcare provider will administer TYGIV he/she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use TYGIV

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

4. Possible side effects

TYGIV can have side effects.

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

If any of the following happens, stop using TYGIV and tell your doctor immediately or 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 allergic reaction to TYGIV. You may need urgent medical attention or further hospitalisation.

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

- 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)
- acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
- jaundice (yellow colouration of the skin and eyes)
- liver injury, liver failure (symptoms may include yellowing of skin and eyeballs, nausea, vomiting, sleepiness, confusion, abdominal swelling).

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 (a swollen painful area on the body, filled with pus, caused by an infection), various infections
- laboratory tests show a decreased ability to form blood clots (prolonged activated partial thromboplastin time, prolonged prothrombin time)
- low protein levels in the blood
- low blood sugar
- dizziness
- nausea, vomiting, diarrhoea
- stomach pain, dyspepsia (stomach-ache and indigestion), anorexia (loss of appetite)
- increases in liver enzymes
- hyperbilirubinaemia (excess of bile pigment in the blood)
- pruritus (itching), rash
- headache
- vein inflammation (redness, swelling, warmth, tenderness)
- poor or slow wound healing
- increase in amylase, which is an enzyme found in the salivary glands and pancreas, increased blood urea (BUN).

Less frequent side effects

- increased INR (a laboratory test that shows that your blood is taking longer to clot)
- low fibrinogen levels in the blood (a protein involved in blood clotting)
- low platelet levels in the blood (thrombocytopenia), which may lead to an increased bleeding tendency and bruising
- injection site reaction (pain, swelling).

Side effects with unknown frequency

- Superinfections with other organisms (fungi and bacteria), including pseudomembranous colitis. 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
- severe skin reactions, including Stevens-Johnson syndrome (a skin rash, which may lead to severe blistering and peeling of the skin)

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 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 TYGIV.

5. How to store TYGIV

Store all medicines out of reach of children.

TYGIV will be stored in the hospital in the appropriate conditions.

The unopened vial will be stored at or below 25 °C.

Prepared solution: Once the powder has been made into a solution and diluted ready for use, it should be given to you almost immediately. If necessary, it could be stored at room temperature (not above 25 °C) for up to 24 hours or at 2 °C to 8 °C for up to 48 hours following immediate transfer of the reconstituted solution into the infusion bag.

Do not use TYGIV after the expiry date which is stated on the vial.

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

6. Contents of the pack and other information

What TYGIV contains

- **The active substance** is tigecycline, as tigecycline dihydrate. Each vial contains 50 mg tigecycline. After reconstitution, 1 mL solution contains 10 mg of tigecycline.
- **The other ingredients** are lactose monohydrate, hydrochloric acid and sodium hydroxide.

What TYGIV looks like and contents of the pack

TYGIV is an orange lyophilised powder or cake.

TYGIV is packaged 10-mL type I colourless glass vial with a 20-mm chlorobutyl rubber stopper and a 20-mm aluminium-plastic overseal.

TYGIV is distributed as a single vial or 10-vial tray pack; not all pack sizes may be marketed.

Holder of Certificate of Registration

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