

*Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.*

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# Package Leaflet: Information for the user

## Tigecycline for Injection

### Tygacil®

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**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

1. What Tygacil (Tigecycline) is and what it is used for
2. What you need to know before you take Tygacil (Tigecycline)
3. How to take Tygacil (Tigecycline)
4. Possible side effects
5. How to store Tygacil (Tigecycline)
6. Contents of the pack and other information

#### **1. What Tygacil (Tigecycline) is and what it is used for**

Tygacil (Tigecycline) is an antibiotic of the glycylcycline group that works by stopping the growth of bacteria that cause infections.

Your doctor has prescribed Tygacil (Tigecycline) because you or your child at least 8 years old has one of the following infections:

- Complicated skin and skin structure infections (cSSTI)
- Complicated intra-abdominal infections (cIAI)
- Community acquired pneumonia

Tygacil (Tigecycline) is only used when your doctor thinks other antibiotics are not suitable.

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## **2. What you need to know before you take Tygacil (Tigecycline)**

### **Do not take Tygacil (Tigecycline)**

- If you are allergic to tigecycline, or any of the other ingredients of this medicine (listed in section 6). If you are allergic to tetracycline class antibiotics (e.g., minocycline, doxycycline, etc.), you may be allergic to tigecycline.

### **Warnings and precautions**

#### **Talk to your doctor before receiving Tygacil (Tigecycline):**

- If you have poor or slow wound healing.
- If you are suffering from diarrhoea before you are given Tygacil (Tigecycline). 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 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 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 suffer from a bleeding disorder or are in treatment with anticoagulant drugs, as this medicine can interfere with blood coagulation.

#### **During treatment with Tygacil (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 Tygacil (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 Tygacil (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**

Tygacil (Tigecycline) is not to be used in children less than 8 years of age due to the lack of data on safety and efficacy in this age group and because it may induce permanent dental defects such as staining on the developing teeth.

### **Other medicines and Tygacil (Tigecycline)**

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tygacil (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.

Tygacil (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 Tygacil (Tigecycline).

Tygacil (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.

### **Pregnancy and breast-feeding**

Tygacil (Tigecycline) may cause foetal harm. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before receiving Tygacil (Tigecycline).

It is not known if Tygacil (Tigecycline) passes into breast milk in humans. Ask your doctor for advice before breast-feeding your baby.

### **Driving and using machines**

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

## **3. How to take Tygacil (Tigecycline)**

Tygacil (Tigecycline) will be given to you by a doctor or a nurse.

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.

The recommended dose in children aged 8 to <12 years is 1.2 mg/kg given every 12 hours intravenously to a maximum dose of 50 mg every 12 hours.

The recommended dose in adolescents aged 12 to <18 years is 50 mg given every 12 hours.

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

### **If you receive more Tygacil (Tigecycline) than you should**

If you are concerned that you may have been given too much Tygacil (Tigecycline), talk to your doctor or nurse immediately.

### **If you miss a dose of Tygacil (Tigecycline)**

If you are concerned that you may have missed a dose, talk to your doctor or nurse immediately.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Pseudomembranous colitis may occur with most antibiotics including Tygacil (Tigecycline). 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.

Very common side effects are (may affect more than 1 in 10 people):

- Nausea, vomiting, diarrhoea.

Common side effects are (may affect up to 1 in 10 people):

- Abscess (collection of pus), infections
- Laboratory measurements of decreased ability to form blood clots
- Dizziness
- Vein irritations from the injection, including pain, inflammation, swelling and clotting
- Abdominal 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
- Poor or slow wound healing
- Headache
- Increase in amylase, which is an enzyme found in the salivary glands and pancreas, increased blood urea nitrogen (BUN).
- Pneumonia
- Low blood sugar
- 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)
- Injection site reaction (pain, redness, inflammation)
- Low protein levels in the blood

Uncommon side effects are (may affect up to 1 in 100 people):

- Acute pancreatitis (inflamed pancreas which may result in severe abdominal pain, nausea, and vomiting)
- Jaundice (yellow coloration of the skin), inflammation of the liver
- Low platelet levels in the blood (which may lead to an increased bleeding tendency and bruising/haematoma)

Rare side effects are (may affect up to 1 in 1,000 people):

- Low fibrinogen levels in the blood (a protein involved in blood clotting)

Not known side effects are (frequency cannot be estimated from the available data):

- 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

- Skin rash, which may lead to severe blistering and peeling of the skin (Stevens-Johnson Syndrome)

## **5. How to store Tygacil (Tigecycline)**

Tigecycline should be stored below 25°C prior to reconstitution. Once reconstituted, tigecycline 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). If the storage conditions exceed 25°C after reconstitution, tigecycline should be used immediately. Alternatively, tigecycline mixed with 0.9% w/v Sodium Chloride Injection I.P. or 5% w/v Dextrose Injection I.P. 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.

Reconstituted solution must be transferred and further diluted for IV infusion.

The Tygacil (Tigecycline) 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 Tygacil (Tigecycline) contains**

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

The other ingredients are lactose monohydrate, hydrochloric acid, and sodium hydroxide.

### **What Tygacil (Tigecycline) looks like and contents of the pack**

Tygacil (Tigecycline) is supplied as a powder for solution for infusion in a vial and looks like an orange powder or cake before it is diluted.

5 ml vials is packaged in Type I, clear glass vials fitted with gray chloro-butyl rubber stoppers and snapoff aluminum crimp seals.

### **Imported and Marketed in India by:**

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Bandra-Kurla Complex, Bandra (East), Mumbai 400 051, India

### **Manufactured by:**

Please refer the outer pack for details.

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