

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

<sup>Pr</sup>**TYGACIL**

#### **Tigecycline**

Read this carefully before you start taking **TYGACIL** and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TYGACIL**.

#### **Serious Warnings and Precautions**

- **TYGACIL is associated with an increased risk of death.**
- **TYGACIL should only be used in situations where alternative treatments are not suitable.**

#### **What is TYGACIL used for?**

**TYGACIL** is an antibiotic medicine. It is used to treat the following serious bacterial infections in adults:

- skin infections
- abdomen infections
- community acquired pneumonia (lung infections caught outside of hospitals or other health care facilities)

Antibacterial drugs like **TYGACIL** treat only bacterial infections. They do not treat viral infections.

#### **How does TYGACIL work?**

**TYGACIL** belongs to the class of medicines called tetracycline antibiotics. It works by helping to stop the growth of bacteria responsible for your infection.

#### **What are the ingredients in TYGACIL?**

Medicinal ingredients: Tigecycline

Non-medicinal ingredients: hydrochloric acid, lactose monohydrate, sodium hydroxide

#### **TYGACIL comes in the following dosage forms:**

**TYGACIL** comes as a powder to be mixed with a specific liquid and injected slowly into a vein.

**TYGACIL** is supplied as a 5 mL single-dose glass vial.

Each **TYGACIL** vial contains 50 mg of tigecycline powder.

#### **Do not use TYGACIL if:**

- you are allergic to tigecycline,
- you are allergic to any other ingredients of **TYGACIL** (see **What are the ingredients in TYGACIL?**),

- you are allergic to other tetracycline antibiotics such as doxycycline, minocycline, and tetracycline.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TYGACIL. Talk about any health conditions or problems you may have, including if you:**

- have other infections.
- have liver problems.
- have any heart conditions.
- are pregnant or planning to become pregnant. **TYGACIL** may cause fetal harm.
- are breastfeeding or planning to breastfeed. It is not known if **TYGACIL** passes into breast milk. There is a possibility of permanent staining of the teeth of the child.

**Other warnings you should know about:**

### **Children**

**TYGACIL** is for use in adults aged 18 and over. There is no experience with the use of **TYGACIL** in children under 18 years of age. **TYGACIL** may cause enamel loss and staining in developing teeth.

**While taking TYGACIL**

- Do not drive or operate machinery. **TYGACIL** may cause side effects such as dizziness.
- **TYGACIL** may make your skin more sensitive to sunlight than it is normally. To protect your skin from sunburn, you should:
  - Wear protective clothing and sunglasses
  - Limit your time in the sun especially between 11 a.m. and 4 p.m.
  - Use sunscreen
  - Avoid using tanning beds
- If you develop severe diarrhea during your treatment with **TYGACIL** or over 2 months after your treatment is finished, call your healthcare professional immediately (see What are possible side effects from using **TYGACIL**? Section below).
- Do not use any medicine to treat your diarrhea without first checking with your doctor.
- Your healthcare professional may order some blood tests for you before and while you are on treatment with **TYGACIL**.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with TYGACIL:**

- anticoagulants (blood thinners) such as warfarin
- contraceptive pill (birth control pill). Talk to your doctor about the need for an additional method of contraception while receiving **TYGACIL**.
- drugs that weaken the immune system such as tacrolimus or cyclosporine. Taking **TYGACIL** may lead to increased levels of these drugs in your body. Tell your healthcare professional if you are taking tacrolimus or cyclosporine so that blood levels can be checked before, during and after taking **TYGACIL**. The dose of tacrolimus or cyclosporine may be adjusted while you are taking **TYGACIL**.

**How to take TYGACIL:**

- Your healthcare professional will give **TYGACIL** by intravenous infusion (slow drip through a needle into a large vein) over a period of 30 to 60 minutes.
- Although you may feel better early in treatment, **TYGACIL** should be used exactly as directed.
- Misuse or overuse of **TYGACIL** could lead to the growth of bacteria that will not be killed by **TYGACIL** (resistance). This means that **TYGACIL** may not work for you in the future.
- Do not share your medicine.
- If your condition does not improve in a few days or if it gets worse, contact your healthcare professional.

**Usual dose:**

The usual adult dose of **TYGACIL** is 100 mg for the first dose, followed by 50 mg every 12 hours.

The length of your treatment depends on the type of infection you have and how your body responds to **TYGACIL**.

**Overdose:**

If you think you, or a person you are caring for, have taken too much TYGACIL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

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

**What are possible side effects from using TYGACIL?**

These are not all the possible side effects you may have when taking TYGACIL. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea
- Vomiting
- Diarrhea
- Abdominal pain
- Dizziness
- Skin rash
- Itching
- Headache
- Abdominal discomfort

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have Clostridium difficile colitis (bowel inflammation). If this occurs, stop taking **TYGACIL** and contact your healthcare professional immediately.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Injection site reaction</b> (pain, redness, inflammation)		√	
<b>Vein irritations from the injection</b> (including pain, inflammation, swelling and clotting)		√	
<b>Fever</b>		√	
<b>Cardiovascular issues:</b> racing heartbeat (palpitations) or fainting		√	
<b>Chills</b>		√	
<b>Chest pain</b>		√	
<b>Decreased platelets</b> (cells in the blood that help the blood clot): <ul style="list-style-type: none"> <li>• Unusual bruising or bleeding</li> <li>• Pinpoint red spots on the skin</li> </ul>		√	
<b>Jaundice:</b> dark urine, yellowness of skin or eye			√
<b>Pancreatitis</b> (Inflammation of the pancreas): severe upper stomach pain, often with nausea and vomiting			√
<b>Pseudotumor cerebri</b> (pressure inside the skull is increased): severe headache, buzzing sound in the ears (tinnitus), severe dizziness, vision changes, severe nausea		√	
<b>Serious Skin Reactions</b> (Stevens Johnson syndrome): redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			√
<b>Allergic reactions:</b> rash, difficulty breathing, tightening of chest, swelling of lips, tongue or throat			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### **Storage:**

The healthcare professional will store the product under appropriate conditions.

Keep out of reach and sight of children.

#### **If you want more information about TYGACIL:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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