

PART III: CONSUMER INFORMATION

Pr **TYGACIL™**
(tigecycline)

This leaflet is part III of a three-part "Product Monograph" published when TYGACIL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TYGACIL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

The name of the medicine you have been given is TYGACIL. Your doctor prescribed TYGACIL because you have one of the following types of serious infections:

Complicated bacterial infection of the skin
Complicated bacterial infection in the abdomen

TYGACIL is for use in patients 18 years of age and over.

What it does:

TYGACIL is an antibiotic that works by helping to stop the growth of bacteria that cause infections.

When it should not be used:

Do not use TYGACIL if you are allergic to tigecycline or tetracycline antibiotics.

What the medicinal ingredient is:

Tigecycline.

What the important nonmedicinal ingredients are:

TYGACIL does not contain any nonmedicinal ingredients.

What dosage forms it comes in:

TYGACIL (tigecycline) for Injection is supplied in a single-dose 5 mL glass vial containing 50mg lyophilized powder for reconstitution, and is an orange cake or powder.

WARNINGS AND PRECAUTIONS

If you develop severe diarrhea, tell your doctor or nurse immediately. Do this even if it occurs several weeks after TYGACIL has been stopped. Diarrhea may mean that you have a serious condition affecting your bowel. You may need urgent Medical care. Do not take any diarrhea medicine without first checking with your doctor.

BEFORE you use TYGACIL talk to your doctor or pharmacist if:

- Bowel problems while using antibiotics or after finishing them, including severe abdominal or stomach cramps, or watery and severe diarrhea.
 - **Other Infections**
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.
 - **Patients who are Pregnant**
TYGACIL may cause fetal harm. If you are pregnant, or are planning to become pregnant, talk to your doctor before receiving TYGACIL.
 - **Patients who are breast-feeding**
It is not known if TYGACIL passes into breast milk. Ask your doctor for advice before breastfeeding your baby.
 - **Patients with Liver Problems**
You should inform your doctor if you have or had liver disease. Depending on the condition of your liver, your doctor may reduce the dose to avoid potential side effects.
 - **Children**
TYGACIL is not recommended in children because there is no experience with the use of TYGACIL in patients under 18 years of age.

TYGACIL, which is similar in structure to tetracycline antibiotics, may cause enamel loss and staining in developing teeth.
 - **Driving and using machines**
TYGACIL may cause side effects such as dizziness. This may impair your ability to drive or operate machinery.
- While Taking TYGACIL:**
- If you develop a racing heartbeat (palpitations) or faint while using TYGACIL, contact your doctor immediately.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with TYGACIL include:

Always tell your doctor if you are taking warfarin or any other medicines, including medicines you buy without a prescription.

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.

PROPER USE OF THIS MEDICATION

Usual adult dose:

TYGACIL is given intravenously (into a vein) and administered to you by your doctor or nurse.

The recommended dose is 100 mg given initially, followed by 50mg every 12 hours, given by intravenous infusion over a period of 30-60 minutes.

It is very important that you continue to receive TYGACIL for as long as your doctor prescribes it. Your doctor will decide how many days of treatment you need.

Overdose:

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

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, TYGACIL may have side effects. The most common side effects are:

- Nausea
- Vomiting
- Diarrhea
- Abdominal pain

Less common side effects are:

- Dizziness
- Headache
- Skin rash
- Injection site reaction (pain, redness, inflammation)
- Vein irritations from the injection including pain, inflammation, swelling and clotting.
- Fever
- Chills
- Jaundice (yellowness of skin or eye)
- Shortness of breath
- Itching

If these become bothersome, contact your doctor

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom / effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor or pharmacist |
|------------------|---|-------------------------------------|----------------------------|---|
| | | Only if severe | In all cases | |
| Common | | | | |
| Uncommon | <ul style="list-style-type: none"> • Injection site reaction • Vein irritations • Shortness of Breath • Fever • Chills • Jaundice | | ✓ ✓ ✓ ✓ ✓ ✓ | |

This is not a complete list of side effects. For any unexpected effects while taking TYGACIL, contact your doctor or pharmacist.

HOW TO STORE IT

TYGACIL will be stored in the hospital in the appropriate conditions. TYGACIL must be kept out of the reach and sight of children. TYGACIL will be given to you only within the “use-by” date of the product.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax: 866-678-6789

By email: cadmp@hc-sc.gc.ca

By regular mail:

National AR Centre

Marketed Health Products Safety and Effectiveness

Information Division

Marketed Health Products Directorate

Tunney's Pasture, AL 0701C

Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals, can be requested by contacting the sponsor, Wyeth Canada at:
1-800-461-8844

This leaflet was prepared by Wyeth Canada.

Last revised: September 8, 2006