

# TYGACIL®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I being treated with Tygacil?

Tygacil contains the active ingredient tigecycline. It is an antibiotic of the tetracycline class in the glycylicycline subcategory that works by stopping the growth of bacteria that cause infections. Your doctor has prescribed Tygacil because you have one of the following types of serious infections: infection of the skin, including those with resistant bacteria, or infection in the abdomen. For more information, see Section [1. Why am I being treated with Tygacil?](#) in the full CMI.

### 2. What should I know before treatment with Tygacil?

You should not be given Tygacil if you have ever had an allergic reaction to Tygacil or an intolerance to lactose. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more

information, see Section [2. What should I know before treatment with Tygacil?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Tygacil and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is Tygacil given?

Tygacil is given through slow infusion “drip” into a vein by your doctor or nurse. More instructions can be found in Section [4. How is Tygacil given?](#) in the full CMI.

### 5. What should I know during treatment with Tygacil?

|                             |  |
|-----------------------------|--|
| <b>Things you should do</b> | <ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Tygacil.</li><li>• If you get severe diarrhoea, tell your doctor or nurse immediately. Do this even if it happens several weeks after treatment with Tygacil has been stopped.</li></ul> |
|-----------------------------|--|

|                                    |   |
|------------------------------------|---|
|                                    | <ul style="list-style-type: none"> <li>• Tell your doctor immediately if you develop severe abdominal pain, nausea and vomiting.</li> <li>• Use an additional method of contraception.</li> </ul> <p>If you become pregnant while taking this medicine, tell your doctor immediately.</p> <ul style="list-style-type: none"> <li>• For more information on "Things you should do" can be found in Section 6 in the full CMI.</li> </ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"> <li>• Do not breastfeed your baby without discussing the risks with your doctor.</li> </ul>  |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how Tygacil affects you.</li> </ul>   |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"> <li>• Tygacil is stored in the pharmacy or on the hospital ward under the correct conditions.</li> </ul>   |

For more information, see Section [5. What should I know during treatment with Tygacil?](#) in the full CMI.

## 6. Are there any side effects?

Side effects of this medicine may include nausea; vomiting; diarrhoea; dizziness; headache; loss of appetite; stomach pain or heartburn; skin rash and itchiness; low sugar levels in blood which can cause blurred vision, difficulty concentrating, slurred speech and drowsiness; bleed or bruise more easily than normal; yellowing of the skin or eyeballs (jaundice); injection site reaction (pain, redness, inflammation, swelling); abscesses or other infections; abnormal healing; sepsis (rapid heart beat / fever); inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting); Stevens-Johnson Syndrome (a skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals); pneumonia; bleeding following injury taking longer to clot; sudden swelling of the lips, face, throat or tongue (allergic reactions). For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# TYGACIL®

tigecycline

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Tygacil. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tygacil.**

**Where to find information in this leaflet:**

- [1. Why am I being treated with Tygacil?](#)
- [2. What should I know before treatment with Tygacil?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Tygacil given?](#)
- [5. What should I know during treatment with Tygacil?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being treated with Tygacil?

**Tygacil contains the active ingredient tigecycline.** It is an antibiotic of the tetracycline class in the glycyclcycline subcategory that works by stopping the growth of bacteria that cause infections.

Your doctor has prescribed Tygacil because you have one of the following types of serious infections:

- Infection of the skin, including those with resistant bacteria
- Infection in the abdomen.

Tygacil will not work against viral infections such as colds or flu.

## **2. What should I know before treatment with Tygacil?**

### **Warnings**

#### **Do not use Tygacil if:**

- you are allergic to tigecycline or have an intolerance to lactose.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

#### **Check with your doctor if you:**

- have previously had an allergic reaction to tetracycline antibiotics. You may have an increased chance of being allergic to Tygacil if you are allergic to tetracyclines.
- have an intolerance to lactose.
- have or have had liver problems. Depending on the condition of your liver, your doctor may need to reduce your dose to avoid potential side effects.

**Your doctor should do blood tests before you start and regularly while you are having treatment with Tygacil.**

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed.

As with many medicines, Tygacil may harm your developing or breastfeeding baby. This may include permanent staining of the child's teeth.

## **Use in children**

There is no experience with the use of Tygacil in children under 18 years of age. Tygacil, like other tetracyclines, may cause enamel loss and staining in developing teeth.

There is no evidence that Tygacil is addictive.

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Tygacil. These include:**

- medicines to treat infections that contain ketoconazole or rifampicin
- medicines that contain ciclosporin or tacrolimus
- warfarin, if you are taking warfarin, your doctor or nurse will check your blood clotting time.
- oral contraceptives (birth control pills). Tygacil may interfere with birth control pills.

**Talk to your doctor about the need for an additional method of contraception while receiving Tygacil.**

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being given Tygacil.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Tygacil.**

## **4. How is Tygacil given?**

### **How much is given**

Your doctor will decide what dose, and how long you will receive it. This depends on your condition and other factors, such as how well your liver is working.



## **How is Tygacil given**

Tygacil is given through slow infusion “drip” into a vein by your doctor or nurse over a period of 30 - 60 minutes every 12 hours.

## **How long to receive Tygacil**

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. How long you receive Tygacil will depend on how severe your infection is and how quickly you respond to treatment.

## **If you receive too much Tygacil**

It is unlikely that you will receive an overdose of Tygacil because a trained nurse or doctor will give it.

**Tell your doctor or nurse immediately if you are concerned that you may have been given too much Tygacil.**

## **If you miss a dose of Tygacil**

**Talk to your doctor or nurse immediately if you are concerned that you may have missed a dose.**

## **5. What should I know during treatment with Tygacil?**

### **Things you should do**

- If you get severe diarrhoea, tell your doctor or nurse immediately. Do this even if it happens several weeks after treatment with Tygacil has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.

### **Do not take any medicine for diarrhoea without first checking with your doctor.**

- Tell your doctor immediately if you develop severe abdominal pain, nausea and vomiting.

These may be symptoms of inflammation of the pancreas.

- Tell your doctor immediately if you realise that you are pregnant while being given Tygacil.

**If you are about to start any new medicines, tell your doctor and pharmacist that you are being given Tygacil.**

**Tell all doctors, dentists and pharmacists who are treating you that you are being given Tygacil.**

## Things you should not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

## Things to be careful of

- Tell your doctor if you get thrush (a fungal infection which can affect the mouth and/or vagina) or any other infection while having, or soon after stopping Tygacil.

Although antibiotics, including Tygacil, fight certain bacteria, other bacteria and fungi may continue to grow. Your doctor will check you for any possible infections and, if necessary, will give you treatment.

- Protect your skin when you are in the sun, especially between 10 am and 3 pm. If outdoors, wear protective clothing and use a 30+ sunscreen.

Tygacil may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or severe sunburn.

## Driving or using machines

**Be careful driving or operating machinery until you know how Tygacil affects you.** Whilst it is unlikely that you will drive or operate machinery when having Tygacil, you need to be aware that Tygacil may cause side effects such as dizziness. This may affect your ability to drive or operate machinery.

## **Drinking alcohol**

No information is available.

## **Looking after your medicine**

Tygacil is stored in the pharmacy or on the hospital ward under the correct conditions.

## **Disposal of Tygacil**

The hospital staff will dispose of any leftover Tygacil.

## **6. Are there any side effects?**

**Tell your doctor or nurse as soon as possible if you do not feel well while you are having Tygacil.**

**Tygacil is effective against certain serious infections for most people but it may have unwanted side effects in some.**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

| Less serious side effects  | What to do  |
|--|---|
| <ul style="list-style-type: none"><li>• Nausea</li><li>• Vomiting</li><li>• Diarrhoea</li><li>• Constipation</li><li>• Increased cough</li><li>• Back pain</li><li>• Dizziness</li><li>• Headache</li><li>• Loss of appetite</li><li>• Heartburn</li><li>• Swelling of your feet, ankles, lower legs, hand or arms</li><li>• Skin rash and itchiness</li><li>• Low sugar levels in the blood (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heart beat).</li></ul> | <p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> |

## Serious side effects

| Serious side effects  | What to do  |
|---|---|
| <ul style="list-style-type: none"><li>● Increased tendency to bleed or bruise more easily than normal</li><li>● Yellowing of the skin or eyeballs also called jaundice</li><li>● Injection site reaction (pain, redness, inflammation, swelling)</li><li>● Swelling and/or clotting; and redness along a vein which is very tender when touched</li><li>● Abscesses or other infections</li><li>● Abnormal healing</li><li>● Sepsis (rapid heart beat, rapid breathing and fever)</li><li>● Inflammation of the pancreas (severe upper stomach pain, often with nausea and vomiting)</li><li>● Stevens-Johnson Syndrome (a skin condition with severe</li></ul> | <p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p> |

| <b>Serious side effects</b>  | <b>What to do</b> |
|--|-------------------|
| blisters and bleeding in the lips, eyes, mouth, nose and genitals) <ul style="list-style-type: none"> <li>● Pneumonia (fever, chills, shortness of breath, cough, phlegm and occasionally blood)</li> <li>● Bleeding following injury taking longer to clot</li> <li>● Sudden onset of signs of allergy such as: rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.</li> </ul> |                   |

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Some of these side effects (for example, abnormal blood test results including low level of protein/platelet in the blood, high levels of liver enzymes, high levels of enzyme found in the salivary glands/ pancreas and

increase in blood urea nitrogen) can only be found when your doctor does tests from time to time to check your progress.

## **After finishing it**

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Tygacil.

- Severe abdominal cramps or stomach cramps
- Watery and severe diarrhoea, which may also be bloody
- Fever in combination with one or both of the above.

These are serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention.

**Do not take any medicine for this diarrhoea without first checking with your doctor.**

Ask your doctor or pharmacist if you don't understand anything in these lists.

Do not be alarmed by the lists of possible side effects. You may not experience any of them.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side



effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Tygacil contains

|   |                     |
|---|---------------------|
| <b>Active ingredient<br/>(main ingredient)</b>      | tigecycline         |
| <b>Other ingredients<br/>(inactive ingredients)</b> | lactose monohydrate |
|   | sodium hydroxide    |
|   | hydrochloric acid   |

**Do not take this medicine if you are allergic to any of these ingredients.**

Each Tygacil vial contains 50 mg of tigecycline as the active ingredient.

## **What Tygacil looks like**

Tygacil is an orange powder supplied in glass vials. Dissolving the powder in a sterile liquid makes a solution for injection. After mixing, the solution is a yellow to orange colour.

Aust R 147450

## **Who distributes Tygacil**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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