

TYGACIL®

Tigecycline

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tygacil. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Tygacil against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Tygacil is used for

Tygacil 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
- Infection in the abdomen.

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, like other tetracyclines, may cause enamel loss and staining in developing teeth.

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

There is no evidence that Tygacil is addictive.

Tygacil is available only with a doctor's prescription.

Before you are given Tygacil

When you must not be given it

You should not be given Tygacil you have an allergy to:

- tigecycline
- any of the ingredients listed at the end of this leaflet.

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.

Do not have Tygacil after the expiry date (Exp. Date) printed on the pack has passed.

If you take this medicine after the expiry date it may not work.

Talk to your doctor if you are not sure whether you should be given Tygacil.

Before you are given it

You must tell your doctor if:

- **You are allergic to tetracycline antibiotics.**
You may have an increased chance of being allergic to Tygacil if you are allergic to tetracyclines.
- **You are pregnant or breastfeeding.**

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

- **You 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.

If you have not told your doctor or nurse about any of the above, tell them before you are given Tygacil.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a 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 cyclosporin
- 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.

How Tygacil is given

How Tygacil will be given

Tygacil is given as an injection into a vein and administered to you by your doctor or nurse.

How much you will be given

The recommended dosage is 100 mg for the first dose, followed by 50 mg every 12 hours.

How long you will 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 more Tygacil than you should (overdose)

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

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

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.

While you are receiving Tygacil

Things you must 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 realise that you are pregnant while taking Tygacil.

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 15+ 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.

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.

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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

The most common side effects of Tygacil are:

- Nausea
- Vomiting
- Diarrhoea

Other less common side effects include:

- Dizziness
- Headache
- Loss of appetite
- Stomach pain or heartburn
- Increased bleeding tendency
- Skin rash and itchiness
- Yellowing of the skin or eyeballs also called jaundice
- Injection site reaction (pain, redness, inflammation, swelling)
- Swelling and/or clotting; and redness along a vein which is very tender when touched
- Abscesses or other infections
- Abnormal healing

Elevated levels of proteins or liver enzymes in the blood may also be observed by your doctor.

Less often, serious effects have occurred in people taking Tygacil.

Tell your doctor immediately if you notice any of the following:

- Sepsis (rapid heart beat, rapid breathing and 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 (fever, chills, shortness of breath, cough, phlegm and occasionally blood)
- Low sugar levels in the blood (sweating, weakness, hunger, dizziness, trembling, headache,

flushing or paleness, numbness, having a fast, pounding heart beat)

- Increased tendency to bleed or bruise more easily than normal
- Bleeding following injury taking longer to clot
- 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.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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 rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

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 this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After receiving Tygacil

Storage

The hospital will store Tygacil under the correct conditions. Tygacil must be kept out of the reach and sight of children. Tygacil will be given to you only within the "Exp. Date" date of the product.

Product description

What it 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.

Ingredients

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

It also contains:

- lactose monohydrate

It does not contain any preservatives.

Supplier

Tygacil is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

Australian Registration Number

AUST R 147450.

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