

TEICOPLANIN MYLAN

Teicoplanin, powder for injection, 400 mg



What is in this leaflet

Please read this leaflet carefully before you are given Teicoplanin Mylan.

This leaflet answers some common questions about Teicoplanin Mylan.

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 being given Teicoplanin Mylan against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Teicoplanin Mylan is used for

Teicoplanin Mylan contains the active ingredient teicoplanin. It belongs to a group of medicines called antibiotics.

Teicoplanin Mylan is used to treat bacterial infections. It is used to kill bacteria responsible for infections which can occur in your blood, bones or joints.

This antibiotic is generally used when the bacteria causing the infection are not satisfactorily eliminated by other antibiotics (e.g. penicillin) or when patient may be allergic to other antibiotics.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

There is no evidence that this medicine is addictive.

Before you are given Teicoplanin Mylan

When you must not be given it

Do not receive Teicoplanin Mylan if you have an allergy to:

- any medicine containing teicoplanin.
- any of the ingredients listed at the end of this leaflet.

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

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to

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

- any other medicines, including to any other antibiotic (especially an antibiotic called vancomycin).
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Kidney problems
- Liver problems

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Teicoplanin Mylan is not recommended to be used during pregnancy.

It is not known whether Teicoplanin Mylan passes into breastmilk

Your doctor can discuss with you the risks and benefits involved of being given Teicoplanin Mylan if you are pregnant, planning to fall pregnant, are breastfeeding or planning to breastfeed

If you have not told your doctor about any of the above, tell them before you are given Teicoplanin Mylan.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are being given Teicoplanin Mylan.

Some medicines may interfere with Teicoplanin Mylan. These include:

- aminoglycoside antibiotics, medicines used to treat bacterial infections
- amphotericin, medicine used to treat fungal infections
- cyclosporin, medicine used to help control your body's immune system
- cisplatin, a medicine used in the treatment of some cancers
- frusemide, a medicine used to remove excess fluid in the body
- ethacrynic acid, a medicine used to help the kidneys get rid of salt and water

These medicines may be affected by Teicoplanin Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

How Teicoplanan Mylan is given

How much will be given

On the first day of treatment most patients generally receive TWO doses of Teicoplanin Mylan, 12 hours apart. During the following days, most patients receive ONE dose each day. After the first day, the daily dose varies between 6 mg and 12 mg for each kilogram of body weight, depending on the type of infection. An adult of normal weight (around 70 kg) would therefore receive a single daily dose of between 400 mg and 800 mg.

Teicoplanin Mylan can be given to children from 2 months of age. The dose to be given is calculated according to the weight of the patient.

Patients with kidney problems may need lower doses (or doses less often) than other patients. Your doctor will calculate how much Teicoplanin Mylan you require if you have kidney problems

How it is given

The vial of Teicoplanin Mylan powder should be mixed carefully with a recommended sterile solution, to form a clear solution. The solution may be injected directly into a vein over about 5 minutes, or it may be mixed with other sterile solutions and delivered into a vein from a 'drip' bottle or bag over about 30 minutes. Teicoplanin Mylan solution may also be injected directly into a muscle.

How long it will be given for

If you have an infection in your blood, you will probably need to receive a daily injection of Teicoplanin Mylan for 2 to 4 weeks. If you have an infection in any bones or joints, you may require a daily injection of Teicoplanin Mylan for 3 to 6 weeks.

If you forget to it

If you or a carer are giving you Teicoplanan Mylan at home and you miss a dose contact your healthcare professional immediately to find out what you need to do to make up for the missed dose.

If you have trouble remembering to give yourself your medicine, ask your pharmacist or healthcare professional for some hints.

While you are being given Teicoplanin Mylan

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given Teicoplanin Mylan.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while being given this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests to check your hearing, blood, kidney and liver function from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop receiving your medicine because you are feeling better unless advised t by your doctor or pharmacist.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not completely clear or it may return.

Things to be careful of

Be careful driving or operating machinery until you know how Teicoplanin Mylan affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In case of overdose

If you are given too much (overdose)

Telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given

too much Teicoplanin Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given Teicoplanin Mylan.

This medicine helps people with severe infections of blood, joints or bones but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- local pain and redness at the injection site
- mild rash
- dizziness
- nausea
- headache
- stiffness

They are usually mild and short-lived side effects.

Tell your doctor as soon as possible if you notice any of the following:

- fever
- vomiting
- diarrhoea
- blistering of skin, mouth or genitals
- red rash over the upper part of your body "red man syndrome"
- balance problems
- ringing in the ears
- hearing loss or any hearing problems
- if you suspect a second infection

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- hives or welts on your skin

The above list includes very serious side effects. If you have them, you may have a serious allergic reaction to Teicoplanin Mylan. You may need urgent medical attention or hospitalisation. **Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After being given Teicoplanin Mylan

Storage

Teicoplanin Mylan is usually stored in the pharmacy or on the ward.

If you are being given this medicine to take home keep the injection in the carton until it is time to be given.

Teicoplanin Mylan must be stored in a cool dry place where the temperature stays below 25°C until it is time to be given.

Once the powder for injection in the glass vial has been mixed with the recommended sterile solution to produce the liquid to be injected it should be used immediately, but it may be stored in a refrigerator at 2 - 8°C for up to 24 hours.

The prepared solution MUST NOT be frozen

Product description

What it looks like

Teicoplanin Mylan injection is supplied in a glass vial as a white powder. When the powder is mixed with a sterile solution it makes a clear colourless to yellowish solution which can be used.

Active ingredient:

Teicoplanin Mylan contains 400 mg of teicoplanin as the active ingredient.

Inactive ingredients:

- sodium chloride
- sodium hydroxide

Each vial contains 9 mg sodium.

This medicine does not contain preservatives, lactose, sucrose, gluten, tartrazine or any other azo dyes

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist, doctor or healthcare professional.

Who supplies this medicine

Teicoplanin Mylan is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: (09) 579 2792

Date of Preparation

9 October 2019.
(Based on datasheet dated 9 October 2019)