Teicoplanin Sandoz®

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.

1. Why am I being given Teicoplanin Sandoz?

Teicoplanin Sandoz contains the active ingredient teicoplanin. Teicoplanin Sandoz is an antibiotic. It is used to kill bacteria responsible for infections which can occur in your bones, blood, or joints. For more information, see Section 1. Why am I using Teicoplanin Sandoz? in the full CMI.

2. What should I know before I am given Teicoplanin Sandoz?

Do not use if you have ever had an allergic reaction to Teicoplanin Sandoz or any of the ingredients listed at the end of the CMI. 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 I am given Teicoplanin Sandoz? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Teicoplanin Sandoz 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 will I be given Teicoplanin Sandoz?

Teicoplanin Sandoz should be prepared and administered by a qualified health professional (doctor, pharmacist, or nurse). More instructions can be found in Section 4. How do I use Teicoplanin Sandoz? in the full CMI.

5. What should I know while being given Teicoplanin Sandoz?

Things you should do	 Call your doctor straight away if you notice any symptoms of serious skin reactions, including blistering of your skin, mouth, eyes or genitals, a red scaly widespread rash and blisters accompanied by a fever, or flu-like symptoms and a rash on your face and body with a fever. Remind any doctor, dentist, or pharmacist you visit that you are being given Teicoplanin Sandoz. 	
Things you should not do	 Do not receive more than the recommended dose unless your doctor or pharmacist tells you to. Do not stop receiving Teicoplanin Sandoz because you are feeling better, unless advised by your doctor or pharmacist. 	
Driving or using machines	Be careful driving or operating machinery until you know how Teicoplanin Sandoz affects you.	
Looking after your medicine	Teicoplanin Sandoz is stored in the pharmacy or on the ward.	

For more information, see Section 5. What should I know while being given Teicoplanin Sandoz? in the full CMI.

6. Are there any side effects?

Mild side effects include local pain and redness at the injection site, rash, dizziness, nausea, headache and stiffness. Very serious side effects which may indicate a serious allergic reaction include swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, and hives or welts on the skin. Other serious side effects include blistering of your skin, mouth, eyes or genitals, a red scaly widespread rash with bumps under the skin and blisters accompanied by a fever, flu-like symptoms and a rash on your face followed by an extended rash with a fever, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes, and kidney problems (shown in tests).

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Teicoplanin Sandoz® 1

Teicoplanin Sandoz®

Active ingredient: teicoplanin

Consumer Medicine Information (CMI)

This leaflet provides important information about using Teicoplanin Sandoz. 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 Teicoplanin Sandoz.

Where to find information in this leaflet:

1. Why am I being given Teicoplanin Sandoz?

2.What should I know before I am given Teicoplanin Sandoz?

3.What if I am taking other medicines?

4. How will I be given Teicoplanin Sandoz?

5.What should I know while being given Teicoplanin Sandoz?

6.Are there any side effects?

7.Product details

1. Why am I being given Teicoplanin Sandoz?

Teicoplanin Sandoz contains the active ingredient teicoplanin. Teicoplanin Sandoz is an antibiotic. It is used to kill bacteria responsible for infections which can occur in your bones, blood, or joints.

Teicoplanin Sandoz is generally used when the bacteria causing the infection are not satisfactorily eliminated by other antibiotics (e.g., penicillin), or when may be patients are allergic to other antibiotics.

2. What should I know before I use Teicoplanin Sandoz?

Warnings

Do not use Teicoplanin Sandoz if:

 you are allergic to Teicoplanin Sandoz, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or had any other medical conditions, especially kidney problems or liver problems
- · take any medicines for any other condition
- have allergies to any other medicines, including to any
 of other antibiotic (especially an antibiotic called
 vancomycin) or any other substances, such as foods,
 preservatives, or dyes.
- plan to have surgery

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

Do not receive Teicoplanin Sandoz if you are pregnant or intend to become pregnant. Teicoplanin Sandoz is not recommended to be used during pregnancy.

Do not receive Teicoplanin Sandoz if you are breastfeeding or planning to breastfeed. It is not known whether Teicoplanin Sandoz passes into breast milk.

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 Teicoplanin Sandoz and affect how it works. These include:

- aminoglycoside antibiotics, medicine used to treat bacterial infections
- amphotericin B, medicine used to treat fungal infections
- ciclosporin, medicine used to help control your body's immune system
- cisplatin, a medicine used in the treatment of some cancers
- furosemide (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.

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

4. How will I be given Teicoplanin Sandoz?

How much you will be given

- On the first day of treatment most patients generally receive two doses of Teicoplanin Sandoz, 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 you weigh, depending on what type of infection you have. An adult of normal weight (around 70 kg) would therefore receive a single daily dose of between 400 mg and 800 mg.
- Patients with kidney problems may need lower doses (or doses less often) than other patients. Your doctor can calculate how much Teicoplanin Sandoz you require if you have kidney problems.

- If you have an infection in your blood, you will probably need to receive a daily injection of Teicoplanin Sandoz for 2 to 4 weeks. If you have an infection in any bones or joints, you may require a daily injection of Teicoplanin Sandoz for 3 to 6 weeks
- Follow the instructions provided and continue to receive Teicoplanin Sandoz for as long as prescribed by your doctor.

How is Teicoplanin Sandoz given

- Teicoplanin Sandoz should be prepared and administered by a qualified health professional (doctor, pharmacist or nurse).
- The vial of Teicoplanin Sandoz powder should be mixed carefully with the sterile water, which is included in the pack, to form a clear solution.
- The solution may be injected into a vein directly 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 Sandoz may also be injected directly into a muscle.

If you receive too much Teicoplanin Sandoz

As Teicoplanin Sandoz is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you think you have received too much, of if you experience any unexpected or worrying side effects, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Teicoplanin Sandoz?

During treatment you may have tests to check your blood, your kidneys, your liver and/or your hearing. This is more likely if your treatment will last for a long time, you need to be treated with high doses, you have a kidney problem, you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

Things you should do

- Remind any doctor, dentist, or pharmacist that you visit that you are being given Teicoplanin Sandoz.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given Teicoplanin Sandoz.
- If you become pregnant while you are being given Teicoplanin Sandoz, stop receiving it and tell your doctor or pharmacist immediately.

Call your doctor straight away if you notice:

- blistering of the skin, mouth, eyes or genitals, which maybe symptoms of severe skin reactions called 'Stevens-Johnson Syndrome', or 'Toxic Epidermal Necrolysis', or
- a red scaly widespread rash with bumps under the skin and blisters accompanied by a fever, which maybe symptoms of a severe skin reaction called 'Acute Generalised Exanthematous Pustulosis', or
- flu-like symptoms and a rash on your face, then an extended rash with a high temperature, which may be symptoms of a condition called 'Drug Reaction with Eosinophilia and Systemic Symptoms'.

Things you should not do

- Do not receive more than the recommended dose unless your doctor or pharmacist tells you to.
- Do not use the medicine to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop receiving Teicoplanin Sandoz because you are feeling better, unless advised by your doctor or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Teicoplanin Sandoz affects you.

Looking after your medicine

Teicoplanin Sandoz is stored in the pharmacy or on the ward.

6. Are there any side effects?

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

Injection related • local pain and redness at the injection site Other • rash • dizziness Speak to your doctor or pharmacist if you notice any of these less serious side	Less serious side effects	What to do
• nausea	 local pain and redness at the injection site Other rash dizziness nausea 	doctor or pharmacist if you notice any of these less

Serious side effects

Serious side effects	What to do
 fever vomiting diarrhoea balance problems ringing in the ears problems hearing if you suspect you have a second infection low levels of all types of blood cells (pancytopenia) – the symptoms may include shortness of breath, fatigue, fever, chills, and bruising 	Speak to your doctor or pharmacist as soon as possible if you notice any of these side effects.

Allergic reaction related swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing hives or welts on your skin blistering of the skin, mouth, eyes or genitals - these may be symptoms of something called 'Toxic Epidermal Necrolysis' or 'Stevens-Johnson Syndrome' red scaly widespread rash with bumps under the skin (including your skin folds, chest, abdomen (including stomach), back and arms) and blisters accompanied by fever – these may be symptoms of something called 'Acute Generalised Exanthematous Pustulosis' flu-like symptoms and a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. These may be signs or symptoms of 'Drug Reaction with Eosinophilia and Systemic Symptoms' Other very serious side effects
kidney problems – shown in tests. Frequency or severity of kidney problems may be increased if you

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.

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. 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 Teicoplanin Sandoz contains

Active ingredient	Teicoplanin
(main ingredient)	
Other ingredients	Sodium Chloride
(inactive ingredients)	Water for injections
Potential allergens	Soy

Teicoplanin Sandoz does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes

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

What Teicoplanin Sandoz looks like

Teicoplanin Sandoz is presented in a glass vial as a white powder which your doctor, pharmacist or nurse will mix with the ampoule of sterile water, included in the pack. A clear solution is formed when the powder is mixed with the water.

Available in packs containing one vial of powder for injection and one ampoule of diluent (AUSTR 157812).

Who distributes Teicoplanin Sandoz

Sandoz Pty Ltd ABN 60 075 449 553 54 Waterloo Road Macquarie Park, NSW 2113

Tel: 1800 726 369

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