PACKAGE LEAFLET

Package leaflet: Information for the patient

Teicoplanin 100 mg Powder for Solution for Injection/Infusion or Oral Solution
Teicoplanin 200 mg Powder for Solution for Injection/Infusion or Oral Solution
Teicoplanin 400 mg Powder for Solution for Injection/Infusion or Oral Solution

teicoplanin

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Teicoplanin is and what it is used for

Teicoplanin contains the active substance teicoplanin, which is an antibiotic. It works by killing the bacteria that cause infections in your body.

Teicoplanin is used in adults and children (including newborn babies) to treat bacterial infections of:
- the skin and underneath the skin (sometimes called soft tissue)
- the bones and joints
- the lung
- the urinary tract
- the heart (sometimes called endocarditis)
- the abdominal wall (peritonitis)
- the blood, when caused by any of the conditions listed above

Teicoplanin can be used to treat some infections caused by the *Clostridium difficile* bacteria in the gut. For this, the solution is taken by mouth.

2. What you need to know before you are given Teicoplanin

You must not be given Teicoplanin if you are allergic to teicoplanin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Teicoplanin if:
- you are allergic to an antibiotic called vancomycin
- you have a flushing of your upper part of your body (red man syndrome)
- you have low levels of platelets in the blood (thrombocytopenia)
- you have kidney problems
- you are taking other medicines which may cause hearing problems and/or kidney problems (see "Other medicines and Teicoplanin").

During treatment
If you have a serious allergic reaction when given Teicoplanin such as a red, itchy skin rash (known as nettle rash), swelling of the face, lips, mouth, tongue or throat causing difficulty breathing or swallowing, wheezing, fast heart beat with a feeling you may faint, stop taking this medicine. Tell your doctor or nurse immediately or go to the nearest hospital emergency department (see section 4 'Possible side effects').

If you have serious skin reactions when given Teicoplanin such as a widespread skin rash with blistering or peeling skin, stop taking this medicine and tell your doctor or nurse immediately or go to the nearest hospital emergency department (see section 4 'Possible side effects').

You may have tests to check your blood, kidneys, liver and/or your hearing. This is more likely if:
- your treatment will last for a long time
- you have a kidney problem
- you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

Other medicines and Teicoplanin
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because Teicoplanin can affect the way some other medicines work. Also, some medicines can affect the way Teicoplanin works.

In particular, tell your doctor, pharmacist or nurse if you are taking the following medicines:
- aminoglycosides (other antibiotic medicines such as streptomycin, gentamycin, tobramycin), as they must not be mixed together with Teicoplanin in the same injection. They may also cause hearing problems and/or kidney problems
- colistin (an antibiotic medicine) which may cause hearing problems and/or kidney problems
- amphotericin B (a medicine that treats fungal infections) which may cause hearing problems and/or kidney problems
- ciclosporin (a medicine that affects the immune system) which may cause hearing problems and/or kidney problems
- cisplatin (a medicine that treats certain cancers) which may cause hearing problems and/or kidney problems
- furosemide or etacrynic acid (medicines known as water tablets or diuretics that treat fluid build-up or swelling) which may cause hearing problems and/or kidney problems.

Pregnancy, breast-feeding and fertility
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this medicine.

The use of Teicoplanin is not recommended during pregnancy as it is not known how this medicine will affect the baby. There may be a potential risk to the unborn baby of inner ear and kidney problems.

If you are breast-feeding, ask your doctor, pharmacist or nurse for advice before being given this medicine. It is not known if this medicine is present in breast milk. Your doctor will discuss with you whether it is more beneficial to take this medicine or to breast-feed your child.

There is no evidence that this medicine causes fertility problems.

Driving and using machines
You may have headaches or feel dizzy while being treated with Teicoplanin. If this happens, do not drive or use any tools or machines.

Teicoplanin contains sodium
This medicine contains approximately 11.3 mg of sodium in each vial. This medicinal product contains less than 1 mmol sodium (23 mg) per vial and is essentially "sodium-free", but where more than two vials are used it should be taken into consideration by patients on a controlled sodium diet.

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This medicine contains approximately 9.0 mg of sodium in each vial. This medicinal product contains less than 1 mmol sodium (23 mg) per vial and is essentially "sodium-free", but where more than two vials are used it should be taken into consideration by patients on a controlled sodium diet.

3. How Teicoplanin is given

The recommended doses are:
Use in adults and adolescents (12 years and over) with no kidney problems
Skin and soft tissue, lung and urinary tract infections
- Starting dose (for the first three doses): 400 mg (this equates to 6 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 400 mg (this equates to 6 mg for every kilogram of body weight), given once a day, by injection into a vein or muscle

Bone and joint infections, and heart infections
- Starting dose (for the first three to five doses): 800 mg (this equates to 12 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 800 mg (this equates to 12 mg for every kilogram of body weight), given once a day, by injection into a vein or muscle

Infection caused by the *Clostridium difficile* bacteria
The recommended dose is 100 to 200 mg by mouth, twice a day for 7 to 14 days.

Use in adults and elderly patients with kidney problems
If you have kidney problems, your dose will usually need to be lowered after the fourth day of treatment:
- For people with mild and moderate kidney problems - the maintenance dose will be given every two days, or half of the maintenance dose will be given once a day.
- For people with severe kidney problems or on haemodialysis - the maintenance dose will be given every three days, or one-third of the maintenance dose will be given once a day.

Peritonitis for patients on peritoneal dialysis
The starting dose is 6 mg for every kilogram of body weight, as a single injection into a vein, followed by:
- Week one: 20 mg/L in each dialysis bag
- Week two: 20 mg/L in every other dialysis bag
- Week three: 20 mg/L in the overnight dialysis bag.

Use in babies (from birth to the age of 2 months)
- Starting dose (on the first day): 16 mg for every kilogram of body weight, as an infusion through a drip into a vein.
- Maintenance dose: 8 mg for every kilogram of body weight, given once a day, as an infusion through a drip into a vein.

Use in children (from 2 months to 12 years)
- Starting dose (for the first three doses): 10 mg for every kilogram of body weight, given every 12 hours, by injection into a vein.
- Maintenance dose: 6 to 10 mg for every kilogram of body weight, given once a day, by injection into a vein.

How Teicoplanin is given
The medicine will normally be given to you by a doctor or nurse.
- It will be given by injection into a vein (intravenous use) or muscle (intramuscular use).
- It can also be given as an infusion through a drip into a vein.

Only the infusion should be given in babies from birth to the age of 2 months.
To treat certain infections, the solution may be taken by mouth (oral use).

If you are given more Teicoplanin than you should
It is unlikely that your doctor or nurse will give you too much medicine. However, if you think you have been given too much Teicoplanin or if you are agitated, talk to your doctor or nurse straight away.

If your doctor or nurse forgets to give you Teicoplanin
Your doctor or nurse will have instructions about when to give you Teicoplanin. It is unlikely that they will not give you the medicine as prescribed. However, if you are worried, talk to your doctor or nurse.

If you stop being given Teicoplanin
Do not stop having this medicine without first talking to your doctor, pharmacist or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop your treatment and tell your doctor or nurse straight away or go to the nearest hospital emergency department if you notice any of the following serious side effects:

Uncommon (may affect up to 1 in 100 people)
- sudden life-threatening allergic reaction - the signs may include: a red itchy skin rash (known as nettle rash), swelling of the face, lips, mouth, tongue or throat causing difficulty breathing or swallowing, wheezing, fast heart beat with a feeling you may faint
- an increase in the number of infections you get causing fever, severe chills, mouth ulcers or sore throat. These may be signs of low levels of white blood cells
- deafness

Rare (may affect up to 1 in 1,000 people)
- reddening or rash of the skin on the face, arms, neck or upper body, possibly with signs similar to a serious allergic reaction as described above (red man syndrome)

Not known (frequency cannot be estimated from the available data)
- growth of antibiotic-resistant bacteria (‘superinfection’)
- widespread rash with blistering and peeling of the skin around the mouth, eyes or genitals - these may be signs of “toxic epidermal necrolysis”, “Stevens-Johnson syndrome”, erythema multiforme or ‘drug reaction with eosinophilia and systemic symptoms (DRESS)’. DRESS appears initially as 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.
- fits (seizures)
- producing little or no urine, pain when passing urine, urine is cloudy or dark coloured possibly with lower back pain. These may be signs of serious kidney problems

Other possible side effects include:

Common (may affect up to 1 in 10 people)
- rash, red or itchy skin
- pain
- fever

Uncommon (may affect up to 1 in 100 people)
- unexplained bruising or bleeding for longer than normal. These may be signs of low levels of platelets in the blood
- an increase in some white blood cells which can be seen in a blood test
- increased blood levels of liver enzymes which can be seen in a blood test
- increased blood levels of creatinine which can be seen in a blood test
- hearing loss, ringing, buzzing, whistling or hissing in the ears (tinnitus) or a feeling that you, or things around you are moving
- swelling and redness along a vein that is tender to touch (phlebitis)
- wheezing or coughing
- feeling sick (nausea) or being sick (vomiting), diarrhoea
- dizziness or headache

Rare (may affect up to 1 in 1,000 people)
- infection causing a swelling filled with pus (abscess)

Not known (frequency cannot be estimated from the available data)
- chills

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teicoplanin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label of the vial after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Information about storage and the time to use Teicoplanin, after it has been reconstituted and is ready to use, are described in the "Practical information for healthcare professionals on preparation and handling of Teicoplanin".

6. Contents of the pack and other information

What Teicoplanin contains

- The active substance is teicoplanin. Each vial contains 100 mg, 200 mg or 400 mg teicoplanin.
- The other ingredients are sodium chloride and sodium hydroxide.

What Teicoplanin looks like and contents of the pack
Teicoplanin is a powder for solution for injection/infusion or oral solution.
The powder appears white to off-white. Due to the nature of the product, the powder may be in larger pieces.

The medicine is packaged in:
- a 10 mL colourless glass vial closed with a bromobutyl rubber stopper and flip-off top aluminium overseal.
- a 10 mL colourless glass vial closed with a bromobutyl rubber stopper and flip-off top aluminium overseal.
- a 20 mL colourless glass vial closed with a bromobutyl rubber stopper and flip-off top aluminium overseal.

Teicoplanin is available in packs of 1, 5 and 10 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Generics [UK] Limited
Station Close, Potters Bar, Hertfordshire EN6 1TL, United Kingdom

Manufacturers:
Agila Specialties Polska Sp. z o.o.
10, Daniszewska Str, 03.230 Warsaw, Poland.

Wessling Hungary Kft.
Fóti út 56, 1047 Budapest, Hungary.

Mylan S.A.S.
117 allée des parcs, 69800, Saint Priest, France.

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany	Teicoplanin Mylan 100 mg, 200 mg, 400 mg Pulver zur Herstellung einer Injektions-/Infusionslösung oder einer Lösung zum Einnehmen
France	Téicoplanine Mylan Pharma 100 mg, 200 mg, 400 mg, poudre pour solution injectable/pour perfusion ou solution buvable
Ireland	Teicoplanin 100 mg, 200 mg, 400 mg Powder for Solution for Injection/Infusion or Oral solution
Italy	Teicoplanina Mylan
Poland	Teicoplanin Generics
United Kingdom	Teicoplanin 100 mg, 200 mg, 400 mg powder for solution for injection/infusion or oral solution

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The following information is intended for healthcare professionals only:

Practical information for healthcare professionals on preparation and handling of Teicoplanin.

This medicine is for single use only.

Method of administration
The reconstituted solution may be injected directly or alternatively further diluted.
The injection will be given either as a bolus over 3 to 5 minutes or as a 30-minute infusion.
Only the infusion should be given in babies from birth to the age of 2 months.
The reconstituted solution may also be given by mouth.

Preparation of reconstituted solution

- Reconstitute the solution by adding 1.7 mL of water for injections to the 100 mg powder vial, or 3.14 mL of water for injections to the 200 mg and 400 mg powder vials.
- Slowly inject the appropriate volume of water for injections into the powder vial.
- Gently roll the vial between the hands until the powder is completely dissolved. If the solution does become foamy, then it should be left to stand for about 15 minutes.

The reconstituted solutions will contain 100 mg of teicoplanin in 1.5 mL, 200 mg in 3.0 mL and 400 mg in 3.0 mL.
Only clear and yellowish solutions should be used.
The final solution is isotonic with plasma and has a pH of 7.0-8.0.

Nominal teicoplanin content of vial	100 mg	200 mg	400 mg
Volume of powder vial	10 mL	10 mL	20 mL
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	1.5 mL	3.0 mL	3.0 mL

Preparation of the diluted solution before infusion
Teicoplanin can be administered in the following infusion solutions:

- Sodium chloride 9 mg/mL (0.9%) solution
- Ringer solution
- Ringer-lactate solution
- 5% glucose injection
- 10% glucose injection
- 0.18% sodium chloride and 4% glucose solution
- 0.45% sodium chloride and 5% glucose solution
- Peritoneal dialysis solution containing 1.36% or 3.86% glucose solution.

Shelf life of reconstituted and diluted solution
Chemical and physical in-use stability of the reconstituted and diluted solution prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicine should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution and dilution have taken place in controlled and validated aseptic conditions.

Disposal
Any unused medicine or waste material should be disposed of in accordance with local requirements.