PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Teicoplanin 200 mg Powder and Solvent for Solution for injection/infusion or oral solution
Teicoplanin 400 mg Powder and Solvent for Solution for injection/infusion or oral solution

Teicoplanin

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 is an antibiotic. It contains a medicine called 'teicoplanin'.
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 '*Clostridioides difficile'* bacteria in the gut. For this, the solution is taken by mouth.

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

Do not use 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 had a flushing of your upper part of your body (red man syndrome)
- you have a decrease in platelet count (thrombocytopenia)
- you have kidney problems
- you are taking other medicines which may cause hearing problems and/or kidney problems. You may have regular tests to check if your kidneys and/or liver are working properly (see 'Other medicines and Teicoplanin').

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you are given Teicoplanin.

Tests
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 loading doses (12 mg/kg twice a day)
- you have a kidney problem

- you are taking or may take other medicines that may affect your nervous system, kidneys or hearing.

In people who are given Teicoplanin for a long time, bacteria that are not affected by the antibiotic may grow more than normal – your doctor will check for this.

Other medicines and Teicoplanin
Tell your doctor, pharmacist or nurse if you are using, have recently used or might use 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 as they must not be mixed together with Teicoplanin in the same injection. They may also 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 malignant tumors which may cause hearing problems and/or kidney problems
- water tablets (such as furosemide) – also called 'diuretics' which may cause hearing problems and/or kidney problems.

If any of the above apply to you, (or you are not sure), talk to your doctor, pharmacist or nurse before being given Teicoplanin.

Pregnancy, breast-feeding and fertility
If you are pregnant, think that you might be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before being given this medicine. They will decide whether or not you are given this medicine while you are pregnant. There may be a potential risk of inner ear and kidney problems.
Tell your doctor if you are breast-feeding, before being given this medicine. He/she will decide whether or not you can keep breast-feeding, while you are given Teicoplanin.
Studies in animal reproduction have not shown evidence of 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 less than 1 mmol (0.41 mmol/9.43 mg) sodium per vial, i.e. essentially sodium free.

3. How to use Teicoplanin

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

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

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.

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.

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 a 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 have 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 you forget to have 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 having 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.

Serious side effects
Stop your treatment and tell your doctor or nurse straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:
Uncommon (may affect up to 1 in 100 people)
- sudden life-threatening allergic reaction - the signs may include: difficulty in breathing or wheezing, swelling, rash, itching, fever, chills

Rare (may affect up to 1 in 1000 people)
- flushing of the upper body

Not known (frequency cannot be estimated from the available data)
- blistering of the skin, mouth, eyes or genitals - these may be signs of something called ‘toxic epidermal necrolysis’ or ‘Stevens-Johnson syndrome’ 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.

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Tell your doctor or nurse straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:
Uncommon (may affect up to 1 in 100 people)
- swelling and clotting in a vein
- difficulty in breathing or wheezing (bronchospasm)

- getting more infections than usual - these could be signs of a decrease in your blood cell count

Not known (frequency cannot be estimated from the available data)
- lack of white blood cells – the signs may include: fever, severe chills, sore throat or mouth ulcers (agranulocytosis)
- low levels of all types of blood cells
- kidney problems or changes in the way your kidneys work - shown in tests. Frequency or severity of kidney problems may be increased if you receive higher doses.
- epileptic fits

Tell your doctor or nurse straight away, if you notice any of the side effects above.

Other side effects
Talk to your doctor, pharmacist or nurse if you get any of these:

Common (may affect up to 1 in 10 people)
- Rash, erythema, pruritus
- Pain
- Fever

Uncommon (may affect up to 1 in 100 people)
- decrease in platelet count.
- raised blood levels of liver enzymes
- raised in blood levels of creatinine (to monitor your kidney)
- hearing loss, ringing in the ears or a feeling that you, or things around you are moving
- feeling or being sick (vomiting), diarrhoea
- feeling dizzy or headache

Rare (may affect up to 1 in 1,000 people)
- infection (abscess).

Not known (frequency cannot be estimated from the available data)
- problems where the injection was given - such as reddening of the skin, pain or swelling

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
For UK: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
For IE: HPRA Pharmacovigilance Website: www.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 outer carton and label of the vials after EXP. The expiry date refers to the last day of that month.

For Powder and Solvent:
Store below 25° C. Keep the container in the outer carton in order to protect from light.
For single use only. Discard any unused solution. 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 200 mg or 400 mg of teicoplanin.

One mL of the reconstituted solution contains 66.7 mg or 133.4 mg of teicoplanin.
- The other ingredients are sodium chloride, sodium hydroxide in the powder and water for injections in the solvent.

What Teicoplanin looks like and contents of the pack
Teicoplanin is a powder and solvent for solution for injection/infusion or oral solution.
The powder is a white to off white powder. The solvent is a clear and colourless solution.

The powder is packaged:
- In a Type I, colourless glass vial of useful volume of 10 mL for 200 mg closed with rubber (Ph.Eur., type I) stopper and sealed with aluminium flip-off caps.
- In a Type I, colourless glass vial of useful volume of 22 mL for 400 mg closed with rubber (Ph.Eur., type I) stopper and sealed with aluminium flip-off caps.

Pack Size: Bt x 1 vial x 200 mg + 1 ampoule x 3 mL solvent
Bt x 10 vials x 200 mg + 10 ampoules x 3 mL solvent
Bt x 1 vial x 400 mg + 1 ampoule x 3 mL solvent
Bt x 10 vials x 400 mg + 10 ampoules x 3 mL solvent

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Noridem Enterprises Ltd, Evagorou & Makariou Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer: DEMO S.A., PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece, T: +30 210 8161802, F: +30 210 8161587

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

United Kingdom	Teicoplanin 200 mg Powder and Solvent for Solution for injection/infusion or oral solution
	Teicoplanin 400 mg Powder and Solvent for Solution for injection/ infusion or oral solution
Austria	Teicoplanin Noridem 200 mg Pulver und Lösungsmittel zur Herstellung einer Injektion-/ Infusionslösung oder einer Lösung zum Einnehmen
	Teicoplanin Noridem 400 mg Pulver und Lösungsmittel zur Herstellung einer Injektion-/ Infusionslösung oder einer Lösung zum Einnehmen
Germany	Teicoplanin Noridem 200 mg Pulver und Lösungsmittel zur Herstellung einer Injektions-/ Infusionslösung oder einer Lösung zum Einnehmen
	Teicoplanin Noridem 400 mg Pulver und Lösungsmittel zur Herstellung einer Injektions-/ Infusionslösung oder einer Lösung zum Einnehmen
Greece	Teicoplanin Noridem 200 mg Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση ή πόσιμου διαλύματος
	Teicoplanin Noridem 400 mg Κόνις και διαλύτης για παρασκευή ενεσίμου διαλύματος ή διαλύματος προς έγχυση ή πόσιμου διαλύματος
Spain	Teicoplanin/Noridem 200 mg Polvo y disolvente para solución inyectable y para perfusion o solución oral
	Teicoplanin/Noridem 400 mg Polvo y disolvente para solución inyectable y para perfusion o solución oral
Ireland	Teicoplanin 200 mg Powder and Solvent for Solution for injection/infusion or oral solution
	Teicoplanin 400 mg Powder and Solvent for Solution for injection/infusion or oral solution

This leaflet was last revised in 10/2022.

The following information is intended for medical or healthcare professionals only:

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

This medicine is for single use only. Discard any unused solution. The reconstitution/dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and

discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Method of administration

Teicoplanin should be administered by the intravenous or intramuscular route. The intravenous injection may be administered either as a bolus over 3 to 5 minutes or as a 30-minutes infusion. Only the infusion should be used in neonates.

For *Clostridioides difficile* infection-associated diarrhea and colitis, the oral route is to be used.

Preparation of reconstituted solution

The solution is reconstituted by adding the entire content of the supplied solvent to the 200 mg and 400 mg powder vial. The water is slowly added to the vial, which should be rotated until all the powder is dissolved to avoid foaming. If foam is developed, allow the solution to stand for approximately 15 minutes so that the foam disappears.

Only clear and yellowish solutions should be used.

The reconstituted solutions will contain 200 mg of teicoplanin in 3.0 mL and 400 mg in 3.0 mL.

The final solution is isotonic with plasma and has a pH of 7.2-7.8.

Nominal teicoplanin content of vial	200 mg	400 mg
Volume of powder vial	10 mL	22 mL
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	3.0 mL	3.0 mL

The reconstituted solution may be injected directly or alternatively further diluted, or orally administered.

Preparation of the diluted solution before infusion

Teicoplanin can be administered in the following infusion solutions:

- 0.9% Sodium Chloride (9 mg/mL) solution for infusion
- Ringer Solution
- Ringer-Lactate Solution
- 5% Dextrose (50 mg/mL) solution for infusion
- 0.18% Sodium Chloride (1.8 mg/mL) and 4% Dextrose (40 mg/mL) solution for infusion
- Peritoneal dialysis solution containing Dextrose 13.6 mg/mL (1.36%)
- Peritoneal dialysis solution containing Dextrose 38.6 mg/mL (3.86%)

Shelf life of reconstituted solution:

Following reconstitution with water for injections, chemical and physical in-use stability 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 has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicine:

Chemical and physical in-use stability of the reconstituted 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/dilution has taken place in controlled and validated aseptic conditions.

Disposal

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