PACKAGE LEAFLET: INFORMATION FOR THE USER

Teicoplanin 100 mg Powder and Solvent for solution for injection or infusion or oral solution
Teicoplanin 200 mg Powder and Solvent for solution for injection or infusion or oral solution
Teicoplanin 400 mg Powder and Solvent for solution for injection or 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 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 '*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

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'
- have a flushing of your upper part of your body (red man syndrome)
- have a decrease in platelet count (thrombocytopenia)
- have kidney problems
- are taking other medicines which may cause hearing problems and/or kidney problems. You may have regular tests to check if your blood, 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 kidneys 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.

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 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 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
- cyclosporine – a medicine that affects the immune system which may cause hearing problems and/or kidney problems
- cisplatin – a medicine that treats malignant tumours 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 may 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. They will decide whether or not you can keep breast-feeding, while you are given Teicoplanin.
Studies in animals' 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 and machines.

Teicoplanin contains sodium
Teicoplanin 100 mg Powder and solvent for solution for injection or infusion or oral solution
This medicine contains less than 1 mmol sodium (23 mg) per vial and is essentially 'sodium-free'.

Teicoplanin 200 mg Powder and solvent for solution for injection or infusion or oral solution
Teicoplanin 400 mg Powder and solvent for solution for injection or infusion or oral solution
This medicinal product contains 1.0 mmol (or 24 mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3 How you will be given 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 or muscle.
- Maintenance dose: 12 mg for every kilogram of body weight, given once a day, by injection into a vein or muscle.

Infection caused by '*Clostridium 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 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 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

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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)
- kidney problems or changes in the way your kidneys work - shown in tests
- 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 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 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 vials 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.'

Do not store in a syringe.

6 Contents of the pack and other information

What Teicoplanin contains
- The active substance is teicoplanin. Each vial contains either 100 mg, 200 mg or 400 mg teicoplanin, equivalent to 100,000 IU, 200,000 IU or 400,000 IU, respectively.

After reconstitution, the solutions will contain 100 mg teicoplanin in 1.5 ml, 200 mg teicoplanin in 3.0 ml or 400 mg teicoplanin in 3.0 ml, respectively.
- The other ingredients are
  powder: sodium chloride and, if necessary, sodium hydroxide for pH adjustment *(see end of section 2 for further information about sodium)*
  solvent: water for injections

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 light yellow powder. The solvent is a clear liquid, practically free from particles.

The powder is packaged:
- in a Type I, colourless glass vial of useful volume of 8 ml for 100 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium white overseal.
- in a Type I, colourless glass vial of useful volume of 10 ml for 200 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.
- in a Type I, colourless glass vial of useful volume of 22 ml for 400 mg closed with bromobutyl rubber stopper and plastic flip-off top aluminium blue overseal.

The solvent is packaged in Type I, colourless glass ampoule and contains 1.5 ml for the 100 mg strength and 3.0 ml for the 200 and 400 mg strengths.

Pack size:

– 1 powder vial with 1 solvent ampoule
– 5x1 powder vials with 5x1 solvent ampoules
– 10x1 powder vials with 10x1 solvent ampoules
– 25x1 powder vials with 25x1 solvent ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

United Kingdom	Teicoplanin 100 mg Powder and Solvent for Solution for Injection or Infusion or Oral Solution Teicoplanin 200 mg Powder and Solvent for Solution for Injection or Infusion or Oral Solution Teicoplanin 400 mg Powder and Solvent for Solution for Injection or Infusion or Oral Solution
Germany	Teicoplanin HEXAL 100 mg Teicoplanin HEXAL 200 mg Teicoplanin HEXAL 400 mg
Ireland	Teicoplanin 100 mg Powder and solvent for solution for injection or oral solution Teicoplanin 200 mg Powder and solvent for solution for injection or oral solution Teicoplanin 400 mg Powder and solvent for solution for injection or oral solution

This leaflet was last approved in 11/2017.

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.

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-minutes 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
- Slowly inject the entire content of the supplied solvent 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. Only clear and yellowish solutions should be used.

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

Nominal teicoplanin content of vial	100 mg	200 mg	400 mg
Volume of powder vial	8 ml	10 ml	22 ml
Volume withdrawable from the solvent ampoule for reconstitution	1.8 ml	3.2 ml	3.2 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
– Hartmanns Solution (Compound Sodium Lactate solution)
– 5% dextrose injection
– 0.18% sodium chloride and 4% glucose solution
– Peritoneal dialysis solution containing 1.36% or 3.86% glucose solution.

Shelf life of reconstituted solution and diluted medicinal product:
Chemical and physical in-use stability of the reconstituted solution and diluted medicinal product prepared as recommended has been demonstrated for 24 hours at 2 to 8°C.
From a microbiological point of view, the medicinal product 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.

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

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