

Package leaflet: Information for the user

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

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
2. What you need to know before you are given Teicoplanin
3. How to use Teicoplanin
4. Possible side effects
5. How to store Teicoplanin
6. Contents of the pack and other information

1. What Teicoplanin is and what it is used for

This medicine contains 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 lungs
- 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 also be used to treat some infections caused by bacteria in the gut called ‘*Clostridium difficile*’. 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.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported with the use of teicoplanin. If you develop a serious rash or other skin symptoms as described in section 4, stop taking Teicoplanin and contact your doctor or seek medical attention immediately.

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 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 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.

This medicine contains sodium

This medicine contains about 10 mg sodium (main component of cooking/table salt) in each vial.

This is equivalent to 0.012% of the recommended maximum daily dietary intake of sodium for adult

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 '*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 take 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 take Teicoplanin

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

If you stop taking 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 1,000 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'
- 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 generalized exanthematous pustulosis (AGEP)'
- '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. 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
- low levels of all types of blood cells

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 Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 vial label after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Teicoplanin contains

- The active substance is teicoplanin. Each vial contains either 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 spongy, ivory coloured powder

The powder is packaged in 10 ml (200 mg) or 20 ml (400 mg) glass vials with a rubber stopper and aluminium flip-off cap.

Teicoplanin is supplied in packs of 1 vial.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in 02/2023

Information for healthcare professionals

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 the reconstituted solution:

- Reconstitute the solution by adding 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 final solution has a pH of 7.2-7.8.

The reconstituted solutions will contain 200 mg in 3.0 ml and 400 mg in 3.0 ml.

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

Preparation of the diluted solution before infusion:

Teicoplanin can be administered in the following infusion solutions:

- Sodium chloride 9mg/mL (0.9%)

- Ringer
- Ringer lactate
- Glucose 5%
- Sodium chloride 0.45% + glucose 5%
- Glucose 10%
- Sodium chloride 0.18% + glucose 4%
- Peritoneal dialysis solution containing 1.36% glucose solution
- Peritoneal dialysis solution containing 3.86% glucose solution

Shelf life of reconstituted/diluted solution:

Chemical and physical in-use stability has been demonstrated for 24 hours at $5 \pm 3^{\circ}\text{C}$ for reconstituted solutions and for reconstituted solutions further diluted as shown above.

From a microbiological point of view, the 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 $5 \pm 3^{\circ}\text{C}$, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Disposal

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