Package leaflet: Information for the user
Teicoplanin Altan 200 mg powder for solution for injection/infusion or oral solution
Teicoplanin

Read all of this leaflet carefully before you start using 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 is Teicoplanin Altan and what it is used for

Teicoplanin Altan is an antibiotic. It contains a medicine called "teicoplanin". It works by killing the bacteria that cause infections in your body.

Teicoplanin Altan is used in adults and children (included 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 Altan 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 use Teicoplanin Altan:

Do not use Teicoplanin Altan:
- 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 Altan 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 a decrease in platelet count (thrombocytopenia)

- you have kidney problems
- you are taking other medicines which can 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 Altan).

If any of the above apply to you, tell your doctor, pharmacist or nurse before you are given Teicoplanin Altan.

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 (12mg/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 Altan for a long time, bacteria that are not affected by the antibiotic may grow more than normal – your doctor may check for this.

Other medicines and Teicoplanin Altan
Tell your doctor, pharmacist or nurse if you are using, have recently used or might use other medicines. Teicoplanin Altan can affect the way some other medicines work. Also, other medicines can affect the way Teicoplanin Altan 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 Altan 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 Altan.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.
They will decide whether or not you are given this medicine while you are pregnant. There may be a potential risk or inner ear and kidney problems.
Tell to 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 Altan.
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 Altan. If this happens, do not drive or use any tools or machines.

Teicoplanin Altan contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial and is essentially "sodium-free".

3. How to use Teicoplanin Altan

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 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 mg 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 non 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.

The way to prepare the reconstituted (to be diluted or administered orally or by injection) and diluted solutions is indicated in section 6 of the leaflet.

How Teicoplanin Altan 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 used more Teicoplanin Altan 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 Altan
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 using teicoplanin
Do not stop using 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).

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
- low levels of all types of blood cells

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teicoplanin Altan

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

This medicinal product does not require any special storage condition.

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 throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Teicoplanin Altan contains

Powder vial:
- The active ingredient is teicoplanin. Each vial contains 200 mg of teicoplanin.
- The other ingredients are sodium chloride, hydrochloric acid and sodium hydroxide.

What Teicoplanin Altan looks like and contents of the pack

Powder vial:
Teicoplanin is a powder for solution for injection/infusion or oral solution. The powder is a white or whiteish powder. The reconstituted solution is a clear and colourless or slightly yellowish solution.

The powder is packaged in a type I, colourless glass vial of useful volume of 10 ml for 200 mg closed with bromobutyl rubber stopper and yellow plastic flip-off top aluminium overseal.

Pack size:
- 1 powder vial

Marketing Authorisation Holder and Manufacturer

Holder:

Altan Pharma Ltd
The Lennox Building, 50 South Richmond street
Dublin 2, D02FK02
Ireland

Manufacturer
Altan Pharmaceuticals S.A.
Polígono Industrial de Bernedo, s/n
01118 Bernedo (Álava)
Spain

or

Altan Pharmaceuticals S.A.
Avda. Constitución 198-199. Pol. Industrial Monte Boyal
45950 Casarrubios del Monte (Toledo)
Spain

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Other sources of information

Detailed information on this medicinal product is available on the website of Medicines and Healthcare products Regulatory Agency.

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 3.2 ml of water for injection 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 200 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 7.2-7.8.

Nominal teicoplanin content of vial	200 mg
Volume of powder vial	10 ml
Volume containing nominal teicoplanin dose (extracted by 5 mL syringe and 23 G needle)	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 solution-lactate
- 5% dextrose injection
- 10% dextrose 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 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.