

Package leaflet: Information for the patient

Teicoplanine SUN 200 mg, poeder en oplosmiddel voor oplossing voor injectie/infusie of orale oplossing

Teicoplanine SUN 400 mg, poeder en oplosmiddel voor oplossing voor injectie/infusie of orale oplossing

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

1. What Teicoplanin SUN is and what it is used for

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

Teicoplanin SUN 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 SUN 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 SUN

Do not use Teicoplanin SUN:

- 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 before you are given Teicoplanin SUN 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 blood, kidneys and/or liver are working properly (see 'Other medicines and Teicoplanin SUN').

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 SUN.

Tests

During treatment you may have tests to check your blood, 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 SUN 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 SUN

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is because Teicoplanin SUN can affect the way some other medicines work. Also, some medicines can affect the way Teicoplanin SUN 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 SUN 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 SUN.

Pregnancy and breast-feeding

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 using 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 SUN.

Animal reproduction studies have not shown evidence of fertility problems.

Driving and using machines

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

Teicoplanin SUN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Teicoplanin SUN

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 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 SUN 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 SUN 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 SUN or if you are agitated, talk to your doctor or nurse straight away.

If you forget to have Teicoplanin SUN

Your doctor or nurse will have instructions about when to give you Teicoplanin SUN. 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 SUN

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 or 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' 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 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), diarrhea
- 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teicoplanin SUN

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

This medicinal product does not require any special temperature storage conditions.

Store in the original package.

Information about storage and the time to use Teicoplanin SUN, 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 SUN'.

Do not throw away any medicines via wastewater or household waste. 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 SUN contains

- The active substance is teicoplanin. Each powder vial contains either 200 or 400 mg teicoplanin.
- The other ingredients are sodium chloride (E551) and sodium hydroxide (E524) (for pH adjustment) in the powder, and water for injection in the solvent.

What Teicoplanin SUN looks like and contents of the pack

Teicoplanin SUN is a powder and solvent for solution for injection/infusion or oral solution. The powder is a white-ivory spongy lyophilized powder. The solvent is a clear, colourless and odourless liquid.

The powder is packed:

- in a Type I, 10 ml colourless glass vial for 200 mg closed with a bromobutyl rubber stopper and an aluminium flip-off seal
- in a Type I, 20 ml colourless glass vial for 400 mg closed with a bromobutyl rubber stopper and an aluminium flip-off seal.

The solvent is packed:

- in a Type I, colourless glass ampoule.

Pack sizes:

1 vial with 200 mg powder and 1 ampoule with 3ml solvent

5 vials with 200 mg powder and 5 ampoules with 3ml solvent

10 vials with 200 mg powder and 10 ampoules with 3ml solvent

25 vials with 200 mg powder and 25 ampoules with 3ml solvent

1 vial with 400 mg powder and 1 ampoule with 3ml solvent

5 vials with 400 mg powder and 5 ampoules with 3ml solvent

10 vials with 400 mg powder and 10 ampoules with 3ml solvent

25 vials with 400 mg powder and 25 ampoules with 3ml solvent

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Vergunninghouder:

Sun Pharmaceuticals Industries Europe B.V.

Polarisavenue 87, 2132 JH Hoofddorp, Nederland

Fabrikant:

Sirton Pharmaceuticals S.p.A., Piazza Settembre 2, 22079 Villa Guardia (CO), Italië

In het register ingeschreven onder:

Teicoplanine SUN 200 mg, poeder en oplosmiddel voor oplossing voor injectie/infusie of orale oplossing- RVG 126980

Teicoplanine SUN 400 mg, poeder en oplosmiddel voor oplossing voor injectie/infusie of orale oplossing- RVG 126983

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

Italy	Teicoplanina SUN
The Netherlands	Teicoplanine SUN 200mg 400mg poeder en oplosmiddel voor oplossing voor injectie/infusie of orale oplossing
United Kingdom	Teicoplanin 200mg 400mg powder and solvent for solution for injection/infusion or oral solution

Deze bijsluiter is voor het laatst goedgekeurd in september 2022

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

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

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.

The reconstituted solutions will contain 200 mg of teicoplanin 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 7.2-7.8.

Nominal teicoplanin content of vial	200 mg	400 mg
Volume of powder vial	10 ml	22 ml
Volume withdrawable from the solvent ampoule for reconstitution	3.14 ml	3.14 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 SUN can be administered in the following infusion solutions:

- sodium chloride 9 mg/ml (0.9%) solution
- 1.36%, 3.86%, 5% dextrose injection
- Ringer lactate
- NaCl 0.18% Dextrose 4%.

Shelf life of reconstituted solution

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 has taken place in controlled and validated aseptic conditions.

Shelf life of diluted medicine

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Disposal

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