

Rx Teicoplanin Injection IP

TEICOCAN 200 / 400 mg
Injection

Composition :

Each vial contains :
Teicoplanin IP 200 mg

Each vial contains :
Teicoplanin IP 400 mg

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

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.

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 (DRESS) 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:

- **Amnioglycosides** 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.

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SINGLE DOSE VIAL

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** (from 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
- Storage : Store in a cool, dry & dark place. Protect from moisture.**
- Improper storage may deteriorate the product.

Keep the medicine out of reach of children

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