Package leaflet: Information for the user

Teicoplanin Hikma 100 mg powder for solution for injection/infusion
Teicoplanin Hikma 200 mg powder for solution for injection/infusion or oral solution
Teicoplanin Hikma 400 mg powder for solution for injection/infusion or oral solution

teicoplanin

Read all of this leaflet carefully before you start taking 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 Hikma is and what it is used for

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

Teicoplanin Hikma 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 Hikma can be used to treat some infections caused by '*Clostridioides difficile*' bacteria in the gut. For this, the solution is taken by mouth.

2. What you need to know before you take Teicoplanin Hikma

Do not take Teicoplanin Hikma:
- 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 taking Teicoplanin Hikma:
- if you are allergic to an antibiotic called 'vancomycin'
- if you have had a flushing of your upper part of your body (red man syndrome)

- if you have a decrease in platelet count (thrombocytopenia)
- if you have kidney problems
- if 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 Hikma').

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you take Teicoplanin Hikma.

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 Hikma 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 (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 take Teicoplanin Hikma 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 Hikma
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This is because Teicoplanin Hikma can affect the way some other medicines work. Also, some medicines can affect the way Teicoplanin Hikma 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 Hikma 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 taking Teicoplanin Hikma.

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 taking 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 using this medicine. They will decide whether or not you can keep breast-feeding, while you are given Teicoplanin Hikma. 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 Hikma. If this happens, do not drive or use any tools or machines.

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

3. How to take Teicoplanin Hikma

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): 400 mg (this equates to 6 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 400 mg (this equates to 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): 800 mg (this equates to 12 mg for every kilogram of body weight), given every 12 hours, by injection into a vein or muscle
- Maintenance dose: 800 mg (this equates to 12 mg for every kilogram of body weight), given once a day, by injection into a vein or muscle

Infection caused by '*Clostridioidesdifficile*' 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 Hikma 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 Hikma 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 Teicoplanine Hikma or if you are agitated, talk to your doctor or nurse straight away.

If you forget to take Teicoplanin Hikma
Your doctor or nurse will have instructions about when to give you Teicoplanine Hikma. 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 taking Teicoplanin Hikma
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 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'
- 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
- low levels of all types of blood cells

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

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 HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teicoplanin Hikma

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 Hikma, 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 Hikma'

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 to protect the environment

6. Contents of the pack and other information

What Teicoplanin Hikma contains
- The active substance is teicoplanin. Each vial contains 100 mg, 200 mg or 400 mg teicoplanin
- The other ingredients are: sodium chloride and sodium hydroxide.

What Teicoplanin Hikma looks like and contents of the pack
Teicoplanin Hikma is a white to yellowish powder in a glass vial. Each pack contains one vial .

Teicoplanin is supplied as packs containing 1 vial.

This medicine is authorised in the Member States of the European Economic Area under the following name:

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

Austria	Teicoplanin Hikma 100 mg Pulver zur Herstellung einer Injektions-/Infusionslösung oder einer Lösung zum Einnehmen Teicoplanin Hikma 200 mg Pulver zur Herstellung einer Injektions-/Infusionslösung oder einer Lösung zum Einnehmen Teicoplanin Hikma 400 mg Pulver zur Herstellung einer Injektions-/Infusionslösung oder einer Lösung zum Einnehmen
Spain	Teicoplanina Hikma 100mg Polvo para solución inyectable y para perfusión EFG Teicoplanina Hikma 200 mg polvo para solución inyectable y para perfusión EFG Teicoplanina Hikma 400 mg polvo para solución inyectable y para perfusión EFG
France	Teicoplanine Hikma 100mg poudre pour solution injectable/pour perfusion ou solution buvable Teicoplanine Hikma 200 mg poudre pour solution injectable/pour perfusion ou solution buvable Teicoplanine Hikma 400 mg poudre pour solution injectable/pour perfusion ou solution buvable
Ireland	Teicoplanin Hikma 100 mg powder for solution for injection/infusion

	Teicoplanin Hikma 200mg powder for solution for injection/infusion or oral solution Teicoplanin Hikma 400mg powder for solution for injection/infusion or oral solution
Italy	Teicoplanina Hikma
Netherlands	Teicoplanine Hikma 100mg poeder voor oplossing voor injectie/infusie of orale oplossing Teicoplanine Hikma 200mg poeder voor oplossing voor injectie/infusie of orale oplossing Teicoplanine Hikma 400mg poeder voor oplossing voor injectie/infusie of orale oplossing
Portugal	Teicoplanina Hikma
United Kingdom (Northern Ireland)	Teicoplanin 100mg Powder for solution for Injection/infusion or oral solution Teicoplanin 200mg Powder for solution for Injection/infusion or oral solution Teicoplanin 400mg Powder for solution for Injection/infusion or oral solution

Marketing Authorisation Holder

Hikma Farmacêutica (Portugal) S.A.
Estrada do Rio da Mó. 8, 8A e 8B - Fervença
2705-906 Terrugem SNT, Portugal

Manufacturer

Hikma Italia SpA
Viale Certosa, 10
IT-27100 Pavia
Italy

This leaflet was last revised in June 2025

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

Practical information for healthcare professionals on preparation and handling of Teicoplanin Hikma.

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

- The powder should be reconstituted with water for injections (1.5 ml – 100 mg, 3.14 ml – 200/400 mg).
- 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 100 mg of teicoplanin in 1.5 ml, 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 6.0-8.0.

Nominal teicoplanin content of vial	100 mg	200 mg	400 mg
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 Hikma can be administered in the following infusion solutions:

- Sodium chloride 9 mg/ml (0.9%) solution
- Ringer solution
- Ringer-lactate solution
- 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
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:
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/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.