

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vancosan 500 mg, Powder for solution for infusion

Vancosan 1000 mg, Powder for solution for infusion

Vancomycin

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Vancosan is and what it is used for

This medicine contains the active substance vancomycin, which is an antibiotic. Vancosan is used to treat severe bacterial infections caused by bacteria resistant to other antibiotics and for patients who are allergic to beta-lactam antibiotics, e.g. penicillin:

- inflammation of the inner heart membrane
- infections of the bones and joints
- inflammation of the lung
- blood poisoning
- soft tissue infection

Vancomycin can also be used before surgery to prevent possible infections.

2. What you need to know before you use Vancosan

Do not use Vancosan

- if you are allergic to vancomycin.

Warnings and precautions

Talk to your doctor before using Vancosan if you:

- suffer or have suffered from an acute failure of the kidney as well as in case of impaired kidney function.
- suffer from impaired hearing function or have previously experienced hearing loss.
- are also taking medicinal products which can harm the ears (e.g. aminoglycoside antibiotics).

- have previously had an allergic reaction to the medicinal substance teicoplanin, since then there is an increased risk of being allergic to Vancosan as well.
- suffer from severe persistent diarrhoea during or after treatment with Vancosan. In this case contact your doctor immediately. Do not take any anti-diarrhoeic medicine without consulting your doctor.

Other medicines and Vancosan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- **Medicines potentially harmful to kidney and hearing:** If you simultaneously receive vancomycin and other medicinal products potentially harmful to kidney and hearing function (e. g. aminoglycoside antibiotics), this harmful effect can be increased. In such cases, a careful and regular control of the kidney and the hearing function is necessary.
- **Anaesthetics:** The use of anaesthetics increases the risk of getting certain side effects of vancomycin like drop of blood pressure, skin erubescence, nettle rash and itching.
- **Muscle relaxants:** If you simultaneously receive muscle relaxants (e.g. succinylcholine), their effect can be intensified or prolonged.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

Vancomycin crosses the placenta and there is a risk of toxicity for the ears and kidneys of the foetus. Therefore, if you are pregnant, your doctor should only give you vancomycin if clearly necessary and after careful consideration of benefits and risks.

Vancomycin passes into breast milk. Since the baby might be affected by this medicinal product, it should be used during breastfeeding only if other antibiotics have failed. You should discuss with your doctor the possibility of stopping breastfeeding.

Driving and using machines

Vancosan has no or negligible influence on the ability to drive and use machines.

3. How to use Vancosan

Administration:

Vancosan is always administered by healthcare personnel. It will be given as an infusion (into a vein). Your doctor will inform you about the necessary duration and frequency of administration of Vancosan.

Dosage:

- **Patients with normal kidney function , adults and children from 12 years**

The usual dose is 500 mg every 6 hours or 1 g every 12 hours.

- **As prevention before a surgery against bacterial infections**

Adults receive 1000 mg prior to surgery and depending on time and type of surgery, the dose of 1000 mg of vancomycin can also be given 12 hours after the surgery.

- **Children (1 month to 12 years)**

The usual daily dose is 40 mg/kg body weight, mostly in 4 single doses, that is 10 mg/kg body weight every 6 hours.

- **Infants up to 1 month**

For infants and new-borns the doses can be lower.

0-7 days: Initial dose of 15 mg/kg body weight and maintenance doses of 10 mg/kg body weight every 12 hours.

7-30 days: Initial dose of 15 mg/kg body weight and maintenance doses of 10 mg/kg body weight every 8 hours.

- **Premature babies and elderly patients**

The dosage must be adjusted for premature babies because their kidneys are not fully functional yet.

In elderly people the dosage of vancomycin must be adapted because kidney function naturally decreases with age. This may require the monitoring of vancomycin levels in your blood.

Treatment duration

The treatment duration depends on severity of the infection as well as on the clinical and bacteriological progress.

If the administration of Vancosan has been forgotten

A double dose must not be given to make up for a forgotten dose. A forgotten dose should only be given before the next regular dose if the time span between the administrations is still long enough.

If the treatment with Vancosan is interrupted or untimely discontinued

Low dosage, irregular administration or premature therapy discontinuation can compromise the outcome of the therapy or lead to relapses, whose therapy is more difficult. Please follow the instructions of your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Vancosan can cause side effects, although not everybody gets them.

The most common side effects are pain, swelling and inflammation of veins at the infusion site and pseudo-allergic reactions when intravenous infusion of Vancosan is carried out too fast.

Common side effects, occurring in 1 to 10 out of 100 treated patients:

Drop of blood pressure, breathlessness (dyspnoea), wheezy breathing (stridor), acute rash (exanthema), mucous membrane inflammation, itching (pruritus), nettle rash (urticaria), impaired kidney function which is mainly recognisable by elevated creatinine or urea concentrations in your blood, inflammation of the veins (phlebitis), erubescence of the upper body („red neck“ or „red man syndrome“), pain and spasm of the chest or back muscles.

Uncommon side effects, occurring in 1 to 10 out of 1000 treated patients:

Transient or persistent impairment of the hearing function.

Rare side effects, occurring in 1 to 10 out of 10,000 treated patients:

Cardiac arrest, drop or elevation of the number of certain blood cells, ringing in the ears (tinnitus), feeling of dizziness or “spinning” (vertigo), feeling sick (nausea), skin disease with blebs (bullous dermatosis), inflammation of the kidneys (interstitial nephritis) and / or acute failure of the kidney, hypersensitivity (anaphylactoid) reactions with symptoms like drug fever and chills.

Very rare side effects, occurring in less than 1 out of 10,000 treated patients:

Severe skin reactions with life-threatening general symptoms (e. g. exfoliative dermatitis, Stevens-Johnson-syndrome or Lyell-syndrome), inflammation of blood vessels, often with skin rash (vasculitis), sudden formation of pustules within large swollen areas (AGEP), bacterial inflammation of the bowel (pseudomembranous colitis).

Side effects of unknown frequency and single reported cases:

Drug reaction that causes rash, fever, inflammation of internal organs, abnormalities of your blood and systemic illness (DRESS), acute necrosis in the kidney tissue.

Severe anaphylactoid reactions are possible during or short time after fast intravenous infusion. The reactions disappear after the infusion was stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Vancosan

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Keep the vial in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer carton and the label after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice particulate matter or a discoloration of the solution for infusion.

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 Vancosan contains**

- The active substance is vancomycin hydrochloride. Each vial contains vancomycin hydrochloride corresponding to 500 mg or 1000 mg vancomycin (as vancomycin hydrochloride), respectively.
- There are no other ingredients.

What Vancosan looks like and contents of the pack

Fine powder, white with pink to brown glimmer.

Vancosan is available in packages with 1, 5 or 10 glass vials with a rubber stopper and a flip-off cap.

Marketing authorisation holder

MIP Pharma GmbH
Kirkeler Str. 41
66440 Blieskastel
Germany
Phone: 0049 (0) 6842 9609 0
Fax: 0049 (0) 6842 9609 355

Manufacturer

Chephasaar Chem.-Pharm. Fabrik GmbH
Mühlstr. 50
66386 St. Ingbert
Germany

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The following information is intended for healthcare professionals only:

The powder must be reconstituted and the resulting concentrate must then be diluted further prior to use.

Preparation of the infusion concentrate

Dissolve the contents of a 500 mg vancomycin vial in 10 ml of sterile water for injections.

Dissolve the contents of a 1000 mg vancomycin vial in 20 ml of sterile water for injections.

One ml of reconstituted solution contains 50 mg of vancomycin.

Preparation of the solution for infusion

The infusion concentrate may be diluted with sterile water for injections, 9 mg/ml sodium chloride or 50 mg/ml glucose.

Vial containing 500 mg vancomycin: To obtain a 5 mg/ml solution for infusion dilute 10 ml of the infusion concentrate with 90 ml of the diluent.

Vial containing 1000 mg vancomycin: To obtain a 5 mg/ml solution for infusion dilute 20 ml of the infusion concentrate with 180 ml of the diluent.

The concentration of vancomycin in the solution for infusion must not exceed 2.5-5 mg/ml.

Appearance of solution for infusion

The solution is to be inspected visually for particulate matter and discolouration prior to administration. The solution must only be used if the solution is clear and free from particles.

Compatibility with intravenous solutions

Vancomycin is compatible with water for injections, 5% glucose solution and physiological sodium chloride solution. Vancomycin solutions are basically administered separately, if the chemical and physical compatibility with another infusion solution is not proven.

To prevent precipitation due to the low pH of vancomycin hydrochloride in solution, all intravenous cannulae and catheters should be flushed with saline.

Important incompatibilities

Vancomycin solutions have a low pH value, which can lead to chemical or physical instability after mixing with other substances. Every parenteral solution should therefore be checked visually for precipitation or changed colour prior to usage.

Vancomycin solutions are not compatible with solutions of penicillins or cephalosporins (betalactam antibiotics). The risk of precipitation increases with higher concentrations of vancomycin. To prevent precipitation, intravenous cannulae and catheters should be flushed with saline between administration of vancomycin and these antibiotics.

Combination therapy

In case of a combination therapy of vancomycin with other antibiotics / chemotherapeutics, the preparations should be administered separately.

Storage after reconstitution

Shelf-life of the prepared infusion solution

The chemical and physical stability of the prepared solution for infusion has been demonstrated for 96 hours at 2-8°C. From a microbiological point of view, the product should be used immediately. If not used immediately, the total 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 2-8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Mode of application and therapy duration

Vancomycin is to be administered as slow intravenous infusion (**not more than 10 mg / min**, as well single doses lower than 600 mg over at least 60 min) and in sufficient dilution (at least 100 ml per 500 mg or at least 200 ml per 1000 mg). Patients with limited fluid intake can also receive a solution of 500 mg / 50 ml or 1000 mg / 100 ml.

Allergic shock (anaphylactic/anaphylactoid reactions) may occur during and immediately after rapid infusion of vancomycin.

Rapid administration (i.e., over several minutes) can cause excessive hypotension (including shock, and, rarely, cardiac arrest), histamine-like response and maculopapular or erythematous rash ("red man's syndrome" or "red neck syndrome"). In case of serious acute hypersensitivity reactions (e.g. anaphylactic reaction), treatment with vancomycin should be discontinued immediately and the usual emergency measures have to be started.

Concomitant use of vancomycin and anaesthetics increases the risk of flushing of the upper body and allergic shock. To reduce the risk of such reactions, vancomycin should be administered for a period of 60 minutes prior to the anaesthetic.