

VANCO MédiS® 1g, lyophilisate for concentrate for solution for infusion

Vancomycin Hydrochloride

Read this leaflet carefully before using this medicine as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it 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 also applies to any side effect not mentioned in this leaflet. See section 4.

What is in this leaflet?

1. What is VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion and in which case is it used?
2. What you need to know before you take VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion?
3. How to take VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion?
4. Possible side effect?
5. How to store VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion?
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1. WHAT IS VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion AND IN WHICH CASE IS IT USED?

It depends on the antibacterial activity and the pharmacokinetic characteristics of Vancomycin.

It takes into account both the clinical studies to which the medicine has given rise and its place in the range of antibacterial products currently available.

It is limited to infections due to germs sensitive to Vancomycin (excluding meningitis), in particular severe staphylococcal infections, including methicillin-resistant staphylococci (common respiratory infections, osteitis, endocarditis, sepsis, etc.), streptococci (including endocarditis), or in subjects allergic to beta-lactams.

Vancomycin has been shown to be active alone or in combination with aminoglycosides in Streptococcus viridans or Streptococcus bovis endocarditis.

In enterococcal endocarditis (e.g. Streptococcus faecalis), Vancomycin must be combined with an aminoglycoside.

Vancomycin is indicated for the prophylaxis of postoperative infections due to Gram + bacteria in : cardiac and vascular surgery, neurosurgery, orthopedic surgery with implantation of prosthetic material.

In case of:

- early reoperation,

- or proven fecoecolization with methicillin-resistant staphylococci (RAMS) (prior antibiotic therapy or hospital stay with SAMR epidemiology), Beta-lactam allergy.

Official recommendations for the appropriate use of antibacterials should be considered.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VANCO MédiS® 1g, lyophilisate for concentrate for solution for infusion?

Never take VANCO MédiS® 1g, lyophilisate for concentrate for solution for infusion:

- if you are allergic to Vancomycin or any of the other components of this medicine mentioned in section 6.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion if:

- you have ever had an allergic reaction to teicoplanin, because this could mean that you are also allergic to Vancomycin,

- you have impaired hearing, particularly if you are elderly (you may have hearing tests during treatment),

- you have kidney problems (you may have blood and urine tests during treatment),

- you are receiving Vancomycin given as an infusion instead of by mouth for the treatment of diarrhea associated with Clostridium difficile infection.

Talk to your doctor or pharmacist or nurse during treatment with Vancomycin if:

- you have been receiving Vancomycin for a long time (you may have blood tests, tests to measure liver and kidney function during treatment),

- you experience a skin reaction during treatment,

- you experience severe allergic reactions (such as anaphylaxis) after using Vancomycin, see your doctor immediately. This could be a sign of inflammation of the intestines (pseudomembranous colitis) which can occur during treatment with antibiotics.

Infants

Vancomycin should be used with caution in premature newborns and young infants, as their kidneys are not fully developed and they may accumulate Vancomycin in the blood. Blood tests may be needed in these children to check Vancomycin levels in the blood.

Concomitant administration of Vancomycin and anesthetic medicines has been associated with reddening of the skin (erythema) and allergic reactions in children. Similarly, the concomitant use of medicines such as aminoglycoside antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs, eg ibuprofen) or amphotericin B (medicine to treat fungal infections) may be harmful to kidneys and therefore more frequent blood tests and measuring the functioning of the kidneys may be necessary.

Other medicines and VANCO MédiS® 1g, powder for concentrate for solution for infusion

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

Medicines potentially harmful to the kidneys (for example: aminoglycosides, iodinated contrast agents, platinum-based chemotherapy products, high doses of metformin and certain antiretrovirals such as pentamidine, foscaet, aciclovir, ganciclovir, foscarnet, valaciclovir, valganciclovir, cidofovir, or tacrolimus). If you receive Vancomycin and other medicines that are potentially harmful to the kidneys at the same time, this harmful effect may be increased. In such cases, careful and regular monitoring of the kidneys is necessary.

Medicines potentially harmful to hearing (for example: aminoglycosides, platinum-based chemotherapy medicines, certain diuretics). If you receive these medicines and Vancomycin at the same time, this harmful effect may be increased. In this case, careful and regular monitoring of the hearing is necessary.

Anesthetics: Using anesthetics increases the risk of developing certain side effects from Vancomycin, such as a drop in blood pressure, flushing of the skin, livers, decreased heart function, and itching.

Muscle relaxants: if you simultaneously take muscle relaxants (for example: succinylcholine), their muscle relaxant effect may be intensified or prolonged.

Oral anticoagulants: if you take warfarin at the same time, the effect of this anticoagulant may be increased.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

During pregnancy the use of this medicine can be considered if necessary. If you discover that you are pregnant during treatment, consult your doctor, as only he can judge the need to continue it.

The administration of this medicine can be considered during breastfeeding if necessary.

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

Driving and using machines

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

This medicine contains sodium. The sodium level is less than 1 mmol per dose administered, i.e. without "sodium".

3. HOW TO TAKE VANCO MédiS® 1g, lyophilisate for concentrate for solution for infusion?

The use of Vancomycin is in hospital with the involvement of medical personnel. Your doctor will decide how much of this medicine you should receive each day and for how long.

Posology

The dose you will receive depends on:

- your age,
- your weight,
- the infection you have,
- how well your kidneys are working,
- your ability to hear,
- any other medicines you are taking.

Intravenous administration

Adults and adolescents (from the age of 12 and over)

The dose is calculated according to your weight. The usual dose of Vancomycin for infusion is 15 to 20 mg per kilogram of body weight. It is usually given every 8 to 12 hours. In some cases, your doctor may decide to give an initial dose of up to 30 mg per kilogram of body weight. The maximum dose per day should not exceed 2 g.

Infants

Children aged 1 month to under 12 years old

The dose is calculated according to your weight. The usual dose of Vancomycin for infusion is 10 to 15 mg per kilogram of body weight. It is usually given every 6 hours.

Premature newborns and full-term newborns (0 to 27 days)

The dose will be calculated according to post-menstrual age : time elapsed since the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (post-natal age).

The elderly, pregnant women and patients with kidney failure may require a different dose.

Intraperitoneal administration

Adults and children

When treating infections related to peritoneal dialysis, your doctor will decide the exact dose of Vancomycin you need.

Method of administration

Intravenous administration

Administration by intravenous infusion means that the medicine flows from a bottle or infusion bag through a tube into your blood vessels and into your body. Your doctor or nurse will always give Vancomycin into the blood and not into the muscle.

The administration of Vancomycin into your veins takes at least 60 minutes.

Intraperitoneal administration

For the treatment of infections related to peritoneal dialysis, Vancomycin will be added to the dialysate during the long exchange.

Ways of preparing the solution

How to prepare Vancomycin solution for intravenous administration

See the section "Information intended exclusively for healthcare professionals".

Duration of treatment

The duration of treatment depends on the infection you have and can last a few weeks.

The duration of treatment may be different depending on each patient's response to treatment.

During treatment, you may have blood tests, urine tests from a urine collection you have given, and possibly hearing tests to check for signs of possible side effects.

If you use more VANCO MédiS® 1g powder for solution for infusion than you should

Not applicable.

If you forget to use VANCO MédiS® 1g powder for solution for infusion

Not applicable.

If you stop taking VANCO MédiS® 1g powder for solution for infusion

Not applicable.

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

4. POSSIBLE SIDE EFFECTS?

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

Vancomycin can cause allergic reactions, although serious allergic reactions (anaphylactic shock) are rare. Tell your doctor immediately if you suddenly have wheezing, difficulty breathing, redness on the upper part of the body, rash or itching.

Common side effects (may affect up to 1 in 10 people):

- low blood pressure,
- shortness of breath, noisy breathing (a high-pitched sound resulting from upper airway obstruction),
- rash and inflammation of the lining of the mouth, itching, itchy rash, hives,
- kidney problems that can be detected mainly through blood tests,
- redness of the upper body and face, inflammation of a vein.

Uncommon side effects (may affect up to 1 in 100 people):

- transient or permanent loss of hearing.

Rare side effects (may affect up to 1 in 1000 people):

- decrease in white blood cells, red blood cells and platelets (blood cells responsible for blood clotting),
- increase in certain white blood cells in the blood,
- loss of balance, noises in the ears, dizziness,
- inflammation of blood vessels,
- nausea (feeling sick),
- kidney inflammation and kidney failure,
- pain in the muscles of the chest and back,
- fever, chills.

Very rare side effects (may affect up to 1 in 10,000 people):

- sudden onset of severe allergic skin reaction with peeling skin or blistering. This may be associated with high fever and joint pain,
- cardiac arrest,
- inflammation of the bowel causing abdominal pain and diarrhea, which may contain blood.

Not known (frequency cannot be estimated from the available data):

- vomiting, diarrhea,
- confusion, drowsiness, lack of energy, bloating, fluid retention, decreased amount of urine passed,
- rash with swelling or pain behind the ears, in the neck, in the groin, under the chin, and in the armpits (swollen lymph nodes), abnormal laboratory results of blood and liver function,
- rash with blisters and fever.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This also applies to any side effect not mentioned in this leaflet. You can also report side effects directly through the national reporting system.

By reporting side effects, you help provide more information about the safety of the medicine.

5. HOW TO STORE VANCO MédiS® 1g, lyophilisate for concentrate for solution for infusion?

Unopened bottles

Store at a temperature not exceeding 30°C.

The reconstituted solution :

It must be used immediately after reconstitution with water for injections. If not used immediately, the solution reconstituted in water for injection is stable for 48 hours at temperature 2°C to 8°C.

The diluted solution :

Chemical and physical in-use stability has been demonstrated for 96 hours at 2°C to 8°C and 24 hours at 25°C with sodium chloride injection 9 mg/ml (0.9%) and glucose injection 50 mg/ml (5%).

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 bottle after (EXP). The expiry date refers to the last day of that month.

Do not dispose of any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What VANCO MédiS® 1g, powder for concentrate for solution for infusion contains?

• The active substance is :

Each vial contains 1025 mg of Vancomycin Hydrochloride equivalent to 1000 mg of Vancomycin.

• The other components are :

Hydrochloric acid (pH 2.5 - 4.5)

Sodium hydroxide (pH 2.5 - 4.5)

What does VANCO MédiS® 1 g, lyophilisate for concentrate for solution for infusion look like and content of the outer packaging?

This medicine is in the form of a lyophilisate for concentrate for solution for infusion. Box of 1 vial.

Marketing authorisation holder and Manufacturer

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Supply conditions: List I

M.A. N°

VANCO MédiS® 1g, box of 1 vial: 9232323H

This leaflet was last reviewed : 09/2023

This is a medicine
- A medicine is a product but not like any other product.
- A medicine is a product that affects your health if it is not used properly : it can be health threatening.
- Strictly adhere to the prescription of your doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and your pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, don't increase the doses without doctor's advice.
Keep the medicines out of reach of children

Other

The following information is intended for healthcare professionals only:

Incompatibilities

The pH value of Vancomycin is low. This can lead to chemical or physical instability when mixed with other substances. Therefore, each parenteral solution should, prior to use, be visually inspected for the presence of precipitation or discoloration.

Combination therapy

In combination therapy with Vancomycin and other antibiotics/chemotherapeutic agents, the preparations should be administered separately.

Vancomycin is not compatible with beta-lactams. The risk of precipitation increases with increasing Vancomycin concentrations. It is recommended to flush the infusion lines between the administration of Vancomycin and these antibiotics. It is also recommended to dilute Vancomycin solutions to a concentration equal to or less than 5 mg/ml, (except in special cases, see section 4.2 of the summary of product characteristics (SPC)).

Methods of preparation

How to prepare Vancomycin solution for intravenous administration

The powder must be reconstituted and the resulting reconstituted solution must then be diluted before use.

Prior to administration, reconstituted and diluted solutions should be inspected visually for particulate matter or discoloration. Solutions should only be used if they are clear and free of particles.

A- Preparation of the reconstituted solution

Dissolve the contents of a 1000 mg vial of Vancomycin with 20 mL of water for injections.

NEVER INJECT THE SOLUTION AS IT IS, BUT DILUTE IT AS FOLLOWS:

B- Preparation of the solution for infusion

The reconstituted solution should then be diluted with sodium chloride (0.9% NaCl) or 5% glucose.

Interrupted infusion: the reconstituted solution containing 1000 mg Vancomycin must be diluted with at least 200 mL of solvent.

The desired dose should be administered by slow intravenous infusion over at least one hour, at a maximum rate of 10 mg/min and sufficiently diluted (at least 100 mL, per 500 mg or at least 200 mL per 1000 mg).

Patients requiring fluid restriction may also receive a 500 mg/50 mL or 1000 mg/100 mL solution, despite the increased risk of infusion-related adverse events with these higher concentrations.

Continuous infusion: the reconstituted solution prepared according to the dose to be administered to the patient must be added to a sufficiently large volume of solvent, so that the desired dose can be administered slowly over a period of 24 hours.

The vials are for single use. Unused product should be discarded.

Health education advice

Antibiotics are used to fight infections caused by bacteria. They are not effective against virus infections.

When your doctor chooses to prescribe you an antibiotic it is because it is precisely suitable for your current illness. Despite the action of an antibiotic, some bacteria have the ability to survive and reproduce. This phenomenon is called resistance: it makes certain antibiotic treatments inactive.

Resistance increases through inappropriate use of antibiotics. You risk to foster the set of resistant bacteria and therefore your healing or making the antibiotic inactive, if you do not respect them appropriately:

- the dose to take,
 - the time of taking,
 - the duration of treatment.
- Therefore, to preserve the effectiveness of this medicine:
- 1 – Only use an antibiotic when prescribed by a doctor.
 - 2 – Strictly follow your prescription.
 - 3 – Do not take again an antibiotic without a doctor's prescription, even if you think you are fighting an apparently similar disease.