PATIENT INFORMATION LEAFLET

VANKOPOL 1000 mg lyophilized powder for solution for i.v. infusion and oral use

For intravenous, intranasal or oral administration. Not for intramuscular administration.

Sterile

- ***Active Substance:*** Vancomycin hydrochloride. Each vial contains 1050 mg vancomycin hydrochloride (1.000.000 IU) equivalent to 1000 g lyophilized vancomycin
- ***Excipient(s):*** None.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET.** You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher** or **lower** doses other than what is recommended to you.*

In this leaflet:

1. What is VANKOPOL and what is it used for?
2. Before you are given VANKOPOL
3. How you will given VANKOPOL?
4. Possible side effects
5. How to store VANKOPOL?

headlines are included.

1. What is VANKOPOL and what is it used for?

VANKOPOL contains the active substance vancomycin. Vancomycin is an antibiotic that belongs to a group of antibiotics called "glycopeptides". Vancomycin works by eliminating certain bacteria that cause infections.

VANKOPOL powder is made into a solution for infusion or oral solution.

VANKOPOL is used in in all age groups by infusion for the treatment of the following serious infections:

- Infections of the skin and tissues below the skin,
- Infections of bone and joints.

- An infection of the lungs called “pneumonia”.
- Infection of the inside lining of the heart (endocarditis) and to prevent endocarditis in patients at risk when undergoing major surgical procedures.

Vancomycin can be given orally in adults and children for the treatment of infection of the mucosa of the small and the large intestines with damage to the mucosae (pseudomembranous colitis), caused by the Clostridium difficile bacterium.

2. Before you are given VANKOPOL

Do not use VANKOPOL under the following circumstances:
If,
- you have previously shown signs of hypersensitivity (severe allergy) to VANKOPOL
- you are pregnant or breastfeeding.

USE VANKOPOL with CAUTION
If,
- you have a kidney disorder,
- you are elderly,
- you have a hearing disorder,
- you will get general anesthesia.
- you are taking other medicines:
    - you are taking other antibiotics that can affect your kidneys e.g. Streptomycin, neomycin, gentamicin, kanamycin, amikacin, tobramycin, polymyxin B and colistin
    - you are using strong diuretic drugs such as furosemide and ethacrynic acid (drugs that are given to increase urine production).
    - you are taking cholestyramine (a medicine used to treat high levels of fat in the blood or diarrhea in inflammatory diseases of the gut).

Please tell your doctor if you are taking or have recently taken any other medicines other than those prescribed to you.

Please consult your doctor even if these warnings apply to you at any time in the past.

Women with childbearing potential / Contraception
There is not enough data on the use of VANKOPOL in women with childbearing potential.

Pregnancy

Please consult your physician or pharmacist before taking the drug.

Do not use VANKOPOL if you are pregnant or trying to become pregnant.

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation
Please consult your physician or pharmacist before taking the drug.

VANKOPOL is excreted in breast milk. Therefore, do not use VANKOPOL while breastfeeding.

Ability to drive and use machines
It has no effect on the ability to drive and use machines.

Vital information regarding some of the excipients contained in VANKOPOL
VANKOPOL contains no substance that require warning.

Use in combination with other drugs
Take special care with VANKOPOL if you use:

- Anesthetics – these may cause redness, flushing, fainting, collapse or even heart attacks. You should, therefore, tell your doctor that you are taking VANKOPOL if you are going to have an operation.
- Careful monitoring is required when vancomycin is concomitantly used with nephrotoxic or neurotoxic drugs such as aminoglycosides, bacitracin, polymyxin B, colistin, viomycin (antibiotics) and cisplatin (a chemotherapy drug).
- potent diuretics (strong medicines which are given to encourage the production of urine) such as furosemide.
- It may still be all right for you to be given VANKOPOL. Your doctor will be able to decide what is suitable for you.
- Cholestyramine (a medicine used to treat high levels of fat in the blood or diarrhoea in inflammatory diseases of the gut).

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. How you will be given VANKOPOL?
You will be given VANKOPOL by medical staff while you are in hospital. Your doctor will decide how much of this medicine you should receive each day and how long the treatment will last.

Instructions regarding correct use and dosage/administration frequency:
Dosage:
The dose given to you will depend on:

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

Intravenous administration:

Adults and adolescents (from 12 years and older)
The dosage will be calculated according to your body weight. The usual infusion dose is 15 to 20 mg for each kg 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 for each kg of body weight. The daily dose should not exceed 2 g.

Use in children:
Children aged from one month to less than 12 years of age:
The dosage will be calculated according to your body weight. The usual infusion dose is 10 to 15 mg for each kg of body weight. It is usually given every 6 hours.

Preterm and term newborn infants (from 0 to 27 days)
The dosage will be calculated according to post-menstrual age (time elapsed between 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 a kidney disorder, including those on dialysis, may need a different dose.

Oral administration
Adults and adolescents (from 12 to 18 years)
The recommended dose is 125 mg every 6 hours. In some cases, your doctor may decide to give a higher daily dose of up to 500 mg every 6 hours. The maximum daily dose should not exceed 2 g.

If you suffered other episodes (infection of the mucosa) before you may need different dose and different duration of the therapy.

Use in children (Neonates, infants and children less than 12 years old)
The recommended dose is 10 mg for each kg of body weight. It is usually given every 6 hours. The maximum daily dose should not exceed 2 g.

• **Route and method of administration:**
Intravenous infusion means that the medicinal product flows from an infusion bottle or bag through a tube to one of your blood vessels and into your body. Your doctor, or nurse, will always give VANKOPOL into your blood and not in the muscle.

VANKOPOL will be given into your vein for at least 60 minutes.

If given for treatment of gastric disorders (so called Pseudomembranous colitis), the medicinal product must be administrated as a solution for oral use (you will take the medicine by mouth).

Duration of treatment
The length of treatment depends on the infection you have and may last a number of weeks. The duration of the therapy may be different depending on the individual response to treatment for every patient.
During the treatment, you might have blood tests, be asked to provide urine samples and possibly have hearing tests to look for signs of possible side effects.

• Different age groups:
Use in children:
Into a vein:
The usual intravenous dose is 10 mg/kg given every 6 hours (total daily dose, 40 mg/kg body weight). Each dose should be administered over a period of at least 60 minutes. In newborns and infants, the daily dose may be lower. For 1-week old infants, an initial dose of 10 mg/kg is recommended followed by 15 mg/kg every 12 hours and than every 8 hours for up to 1 month.

Oral use:
Vancomycin 40 mg / kg divided into 3 or 4 can be administered for 7-10 days. The total daily dose does not exceed 2 g.

In elderly:
Vancomycin is used with caution in patients with renal impairment and prior hearing loss due to their effects on the hearing and kidneys. Renal controls and hearing tests are performed to the elderly during treatment.

Special conditions of use:
Renal impairment
In patients with renal insufficiency, vancomycin doses are adjusted by a doctor.

If you have the impression that the effect of VANKOPOL is too strong or weak, talk with your doctor or pharmacist.

If you have taken more VANKOPOL than you should have:
As VANKOPOL will be given to you whilst you are in hospital is unlikely that you will be given too little or too much. However, tell your doctor or nurse if you have any concerns.

If you used more VANKOPOL than was prescribed, tell your doctor or pharmacist.

If you forget to take VANKOPOL:

Your doctor will decide when to give you the missed dose. It is important that you follow the instructions of your doctor for the time of the next dose.

Do not take double dose to make up the dose you have missed.

Possible effects once VANKOPOL treatment is concluded
If you stop treatment before the recommended time, your treatment will be insufficient.

4. Possible side effects
Like all medicines, VANKOPOL may cause side effects in patients sensitive to its ingredients. In patients using vancomycin, ototoxicity can be seen due to the direct effect on the nerves. Many patients had impaired renal function and hearing loss. The use of vancomycin in patients with hearing loss is not recommended.

If any of the following reactions happen, stop taking VANKOPOL and tell your doctor immediately or contact the casualty department at your nearest hospital:

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

These are all very serious side effects. If you experience one of these side effects, it means that you are severely allergic to VANKOPOL. You may need urgent medical attention or to be hospitalized.

The absorption of vancomycin from the gastrointestinal tract is negligible. However, in severe inflammation of the intestinal mucosa, especially in combination with renal insufficiency, adverse reactions that occur when vancomycin is administered parenterally may appear.

Common side effects (may be seen in less than one of 10 patients but more than one of 100 patients):
- Decrease in blood pressure
- Breathlessness, noisy breathing (a high pitched sound resulting from obstructed air flow in the upper airway)
- Rash and inflammation of the lining of the mouth, itching, itching rash, hives
- Redness of upper body and face, inflammation of a vein
- Kidney problems which may be detected primarily by blood tests

Uncommon side effects (may be seen in less than one of 100 patients but more than one of 1.000 patients):
- Temporary or permanent loss of hearing

Rare side effects (may be seen in less than one of 1.000 patients;)
- Decrease in white blood cells, red blood cells and platelets (blood cells responsible for blood clotting)
- Increase in some of the white cells in the blood.
- Loss of balance, ringing in your ears, dizziness
- Blood vessel inflammation
- Nausea (feeling sick)

- Inflammation of the kidneys and kidney failure
- Pain in the chest and back muscles
- Fever, chills

Very rare side effects (may be seen in less than one of 10.000 patients;)
- Sudden onset of severe allergic skin reaction with skin flaking blistering or peeling skin. This may be associated with a high fever and joint pains
- Cardiac arrest
- Inflammation of the bowel which causes abdominal pain and diarrhea, which may contain blood

Not known (Cannot be estimated from the available data):
- Being sick (throwing up), diarrhea
- Confusion, drowsiness, lack of energy, swelling, fluid retention, decreased urine
- Rash with swelling or pain behind the ears, in the neck, groin, under the chin and armpits (swollen lymph nodes), abnormal blood and liver function tests
- Rash with blisters and fever.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store VANKOPOL?
Keep VANKOPOL out of the sight and reach of children, and in its original packaging.

Store at room temperature below 25°C.

In addition, product reconstituted with water for injection is physically and chemically stable at 25°C for 24 hours and at 2-8°C for 96 hours when diluted with 0.9% sodium chloride and 5% dextrose solutions.

Shake/swirl until product is completely dissolved during reconstitution.

Use in compliance with the expiry date

Do not use VANKOPOL after the expiry date which is stated on the packaging.

Do not throw away expired or remained products! Please follow the local regulations.

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THE FOLLOWING INFORMATION IS FOR HEALTHCARE PROFESSIONALS:

6.2. Incompatibilities

Vancomycin solution has a low pH that may cause chemical or physical instability when it is mixed with other compounds. Mixing with alkaline solutions should be avoided.

Mixtures of vancomycin and beta-lactam antibiotic solutions were found to be physically unstable. As the concentration of vancomycin increases, the probability of collapse increases. It is advisable to clean the intravenous sets between the use of these antibiotics. It is also recommended to dilute vancomycin solutions to 5 mg/L or less.

After simultaneous intravitreal injection of vancomycin and ceftazidime, a precipitation was reported. The precipitates were gradually resolved by complete cleaning of the vitreous cavity for two months and improvement of visual acuity.

6.6 Special precautions for disposal and other handling

Preparation of solution

Add 10 ml of water for Injections to the 0.5 g vial and add 20ml of water for injections to the 1g vial. Vials reconstituted in this manner will give a solution of 50mg/ml. FURTHER DILUTION IS REQUIRED. Please read instructions which follow:

Intermittent infusion is the preferred method of administration. Reconstituted solutions containing 500 mg vancomycin must be diluted with at least 100 ml diluent or 1000 mg vancomycin must be diluted with at least 200 ml diluent. Sodium chloride intravenous infusion or 5% dextrose intravenous infusion are suitable diluents. Reconstituted solutions containing 1g vancomycin must be diluted with at least 200ml diluent. The desired dose should be given by intravenous infusion over a period of at least 60 minutes. If administered over a shorter period of time or in higher concentrations, there is the possibility of inducing marked hypotension in addition to thrombophlebitis. Rapid administration may also produce flushing and a transient rash over the neck and shoulders.

Continuous infusion (should be used only when intermittent infusion is not feasible). 1000 or 2000 mg can be added to a sufficiently large volume of sodium chloride intravenous infusion BP or 5% dextrose intravenous infusion to permit the desired daily dose to be administered slowly by intravenous drip over a 24-hour period.

Oral administration

The contents of vials for parenteral administration may be used.

Common flavoring syrups may be added to the solution at the time of administration to improve the taste.

Any unused medicinal product or waste material should be disposed of in accordance with the local regulations.