PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Vancomycin 500 mg powder for concentrate for solution for infusion
Vancomycin 1 000 mg powder for concentrate for solution for infusion
vancomycin hydrochloride

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.
- 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 Vancomycin is and what it is used for

Vancomycin contains the active ingredient vancomycin. Vancomycin is an antibiotic that belongs to a group of antibiotics called "glycopeptides". Vancomycin works by eliminating certain bacteria that cause infections. Vancomycin powder is made into a solution for infusion or oral solution.

Vancomycin is used 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 bones 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 ***Clostridioides difficile*** bacterium.

2. What you need to know before you are given Vancomycin

You should not be given Vancomycin:
- If you are allergic to vancomycin or any of the other ingredients of this medicine (listed in section 6).
- Into a muscle (intramuscularly), due to the risk of tissue damage (necrosis) at the site of administration.

Warnings and precautions

Serious side effects that may lead to loss of vision have been reported following injection of vancomycin

in the eyes.

Talk to your doctor, hospital pharmacist or nurse before being given Vancomycin if you:
- have ever developed a severe skin rash or skin peeling, blistering, and/or mouth sores after taking vancomycin. Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP)have been reported in association with vancomycin treatment. Stop using vancomycin and seek medical attention immediately if you notice any of the symptoms described in section 4.
- suffered a previous allergic reaction to the antibiotic teicoplanin, because this could mean you are also allergic to vancomycin,
- have a hearing disorder, especially if you are elderly (you may need hearing tests during treatment),
- have a kidney disorder (your will need to have your blood and kidneys tested during treatment),
- are receiving vancomycin by infusion for the treatment of the diarrhoea associated with ***Clostridioides difficile*** infection instead of orally.

Talk to your doctor or hospital pharmacist or nurse during treatment with Vancomycin if you:
- are receiving Vancomycin for a long time (you may need to have your blood, hepatic and kidneys tested during treatment),
- develop any skin reaction during treatment,
- develop severe or prolonged diarrhoea during or after using Vancomycin, consult your doctor immediately. This may be a sign of bowel inflammation (pseudomembranous colitis), which can occur following treatment with antibiotics.

Children
Vancomycin will be used with particular care in premature infants and young infants, because their kidneys are not fully developed and they may accumulate vancomycin in the blood. This age group may need blood tests for controlling vancomycin levels in blood.

Concomitant administration of vancomycin and anaesthetic agents has been associated with skin redness (erythema) and allergic reactions in children. Similarly, concomitant use with other medicines such as aminoglycoside antibiotics, non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen) or amphotericin B (medicine for fungal infection) can increase the risk of kidney damage, and therefore more frequent blood and renal tests may be necessary.

Other medicines and Vancomycin
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
This is especially important if you are taking any of the following medicines:
- Medicines slowing down gut motility,
- Proton pump inhibitors (medicines that reduce the amount of stomach acid).

Particular care should be taken if you are taking other medicines, as some may interact with Vancomycin, for example medicines used for:
- Treatment of infections caused by bacteria (aminoglycosides, bacitracin, polymyxin B, colistin, piperacillin/tazobactam),
- Treatment of tuberculosis (viomycin),
- Treatment of fungal infections (amphotericin B),
- Treatment of cancer (cisplatin),
- Muscle relaxation during surgery,
- Anaesthesia - these anaesthetic agents may cause redness, flushing, fainting, collapse or heart attacks. You should therefore tell your doctor that you are taking Vancomycin if you are going to

have an operation.
- Pain relief such as ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Treatment of oedema (a condition where there is too much water in your body) such as furosemide which is a potent diuretic (strong medicines which are given to encourage the production of urine).

It may still be all right for you to be given Vancomycin, and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Your doctor will then decide if you can receive Vancomycin.

Driving and using machines
Vancomycin should not affect your ability to drive or use machines.

3. How you are given Vancomycin

You will be given Vancomycin 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.

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 per kg of body weight. The maximum 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 the child's body weight. The usual infusion dose is 10 to 15 mg for each kg 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 postmenstrual age (the time elapsed between the first day of the last menstrual period and birth (gestational age) plus the time elapsed after birth (postnatal 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 you 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 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.

Method of administration

Intravenous use
Intravenous infusion means that the medicinal product flows from an infusion bottle or bag through a tube into one of your blood vessels and into your body. Your doctor or nurse will always give vancomycin into your blood and not in the muscle.

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

Oral use
If given for treatment of gastric disorders (so-called pseudomembranous colitis), the medicinal product must be administered as a solution for oral use (you 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 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.

If you are given more Vancomycin than you should receive

As this medicine will be given to you while you are in the hospital, it 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 have any further questions on the use of this medicine, ask your doctor or nurse.

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 get any sudden wheeziness, difficulty in breathing, redness on the upper part of the body, rash or itching.

Stop using vancomycin and seek medical attention immediately if you notice any of the following symptoms:

- **Reddish, non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals, and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome and toxic epidermal necrolysis).**
- **Widespread rash, high body temperature, and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).**
- **A red, scaly, widespread rash with bumps under the skin and blisters, accompanied by fever at the initiation of treatment (acute generalized exanthematous pustulosis).**

The absorption of vancomycin from the gastrointestinal tract is negligible. However, if you have an inflammatory disorder of the digestive tract, especially if you also have a kidney disorder, side effects that occur when vancomycin is administered by infusion may appear.

Common side effects (may affect up to 1 in 10 people)
- Fall in blood pressure,
- Breathlessness, noisy breathing (a high-pitched sound resulting from obstructed airflow in the upper airway),
- Rash and inflammation of the lining of the mouth, itching, itchy rash, hives,
- Kidney problems which may be detected primarily by blood tests,
- Redness of upper body and face, inflammation of a vein.

Uncommon side effects (may affect up to 1 in 100 people)
- Temporary or permanent loss of hearing

Rare side effects (may affect up to 1 in 1,000 people)
- 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 muscle,
- Fever, chills.

Very rare side effects (may affect up to 1 in 10,000)
- 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 diarrhoea, which may contain blood.

Not known (frequency cannot be estimated from the available data)
- Being sick (throwing up), diarrhoea,
- Confusion, drowsiness, lack of energy, swelling, fluid retention, decreased urine output,
- 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.

Reporting of side effects
If you get any side effects, talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Vancomycin

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 the label after"EXP". The expiry date refers to the last day of that month.

No special storage conditions are required.

The stability of the reconstituted and the diluted solution is given at the end of the leaflet in the section intended for healthcare professionals.

6. Contents of the pack and other information

What Vancomycin contains
- The active substance is vancomycin (as hydrochloride).
- There are no other ingredients.

Vancomycin 500 mg:
Each vial contains 500 mg of vancomycin hydrochloride equivalent to 500,000 IU vancomycin.

Vancomycin 1000 mg:
Each vial contains 1000 mg of vancomycin hydrochloride equivalent to 1,000,000 IU vancomycin.

What Vancomycin looks like and contents of the pack

Vancomycin 500 mg and 1000 mg:
An off white to light beige coloured powder.
Type I colourless glass vial with a bromobutyl stopper and aluminium closure with violet (500 mg) or green (1000 mg) plastic flip off cap.

Pack sizes: 1, 5, 10 vial(s)
Not all package sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
hameln pharma gmbh
Inselstraße 1
317 87 Hameln
Germany

Manufacturer
Anfarm Hellas S.A.
61st Km National Road Athens Lamia
320 09 Schimatari Viotias
Greece

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

Croatia:	Vankomicín hameln 500 mg prašak za koncentrát za otopinu za infúziu Vankomicín hameln 1000 mg prašak za koncentrát za otopinu za infúziu
Czech republic:	Vancomycin hameln
Denmark:	Vancomycin hameln
Finland:	Vancomycin hameln
Island:	Vancomycin hameln
Ireland:	Vancomycín 500 mg powder for concentrate for solution for infusion Vancomycin 1000 mg powder for concentrate for solution for infusion
Norway:	Vancomycin hameln
Slovak republic:	Vancomycin hameln 500 mg prášok na koncentrát na infúzny roztok Vancomycin hameln 1000 mg prášok na koncentrát na infúzny roztok
Slovenia:	Vankomycín hameln 500 mg prašok za koncentrát za raztopíno za infundiranje Vankomycín hameln 1000 mg prašok za koncentrát za raztopíno za infundiranje
Sweden:	Vancomycin hameln 500 mg pulver till koncentrát till infusionsvetska, lösning Vancomycin hameln 1000 mg pulver till koncentrát till infusionsvetska, lösning

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Other sources of information

Advice/medical education

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections.

If your doctor has prescribed antibiotics, you need them precisely for your current illness.

Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.

Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:
- dosage
- schedules
- duration of treatment

Consequently, to preserve the efficacy of this drug:
1. Use antibiotics only when prescribed,
2. Strictly follow the prescription,
3. Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.

The following information is intended for healthcare professionals only:

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Instructions for use and handling
Preparation of the reconstituted solution
At the time of use, add 10 ml of water for injections to the 500 mg vial, or 20 ml water for injections to the 1000 mg vial. Vials reconstituted in this manner will give a solution of 50 mg/ml**.** When reconstituted in water, it forms a clear solution.

FURTHER DILUTION IS REQUIRED. Read instructions below.

Preparation of the diluted solution for infusion
Reconstituted solutions containing 50 mg/ml of vancomycin should be further diluted depending on the method of administration. The following solutions are suitable diluents for the preparation of an infusion solution:

- Sodium Chloride 9 mg/ml (0,9 %) solution,
- Glucose 50 mg/ml (5 %) solution,
- Ringer's Lactate solution,
- Sodium Chloride 9 mg/ml (0,9 %) solution and Glucose 50 mg/ml (5 %) solution,
- Sodium Chloride 3 mg/ml (0,3 %) solution and Glucose 33 mg/ml (3,3 %) solution
- Ringers Lactate solution and Glucose 50 mg/ml (5 %) solution

Intermittent infusion is the preferred method of administration.
Reconstituted solutions containing 500 mg vancomycin must be diluted with at least 100 ml diluent.
Reconstituted solutions containing 1000 mg vancomycin must be diluted with at least 200 ml 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).
1 – 2 g can be added to a sufficiently large volume of the suitable above diluent to permit the desired daily dose to be administered slowly by intravenous drip over a 24-hour period.

Prior to administration, parenteral drug products should be inspected visually for particulate matter and discolouration whenever solution or container permits. Only clear and colourless solution free from particles should be used.

Preparation of the oral solution
The contents of vials for parenteral administration may be used.

The content of one Vancomycin 500 mg vial may be reconstituted in 30 ml of water, while the content of one Vancomycin 1000 mg vial may be reconstituted in 30 or 60 ml of water and given to the patient to drink.

Storage
This medicinal product does not require any special storage conditions.

Intravenous administration
Reconstituted solution:
After reconstitution, chemical and physical stability of the concentrate has been demonstrated for up to 24 hours at 25 °C or for up to 96 hours in the refrigerator (2 °C to 8 °C).

Diluted solution:
After further dilution, chemical and physical stability of the solution has been demonstrated for up to 24 hours at 25 °C or 96 hours in the refrigerator at 2 – 8 °C, for the concentration range of 5 mg/ml to 10 mg/ml.

From a microbiological point of view, the product 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 °C to 8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Oral administration
Reconstituted solutions for oral administration may be stored in the refrigerator (2°C to 8°C) for 96 hours.