Package leaflet: Information for the user

Vancomycin Mylan 500 mg powder for solution for infusion
Vancomycin Mylan 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 further questions, please ask your doctor, or pharmacist or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vancomycin Mylan is and what it is used for

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 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
- Infection in the blood linked to the infections listed above.

Vancomycin can be given orally in adults and children for the treament 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. What you need to know before you use Vancomycin Mylan

Do not use Vancomycin Mylan
- if you are allergic to vancomycin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:
Serious side effects that may lead to loss of vision have been reported following the injection of vancomycin in the eyes.

Talk to your doctor or pharmacist or nurse before using vancomycin, if:
- You suffered a previous allergic reaction to teicoplanin because this could mean you are also allergic to vancomycin.
- You have a hearing disorder, especially if you are elderly (you may need hearing tests during treatment).
- You have kidney disorder (you will need to have your blood and kidneys tested during treatment).
- You are receiving vancomycin by infusion for the treatment of the diarrhoea associated to Clostridium difficile infection instead of orally.
- 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.

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).
- You develop any skin reaction during the treatment.
- You 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, nonsteroidal anti-inflammatory agents (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 test may be necessary.

Other medicines and Vancomycin Mylan
Tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The following can react with vancomycin if you take them at the same time, such as medicines for the treatment of:
- infections caused by bacteria (streptomycin, neomycin, gentamycin, kanamycin, amikacin, bacitracin, tobramycin, colimyxin B, colistin, piperacillin/tazobactam),
- tuberculosis (viomycin),
- fungal infections (amphotericin B),
- cancer (cisplatin),

and
- medicines for muscle relaxation during anaesthesia,
- anaesthetic agents (if you are going to have general anaesthesia).

Your doctor may need to monitor your blood and adjust the dosage if vancomycin is given at the same time with other medicines.

Pregnancy and breast-feeding
If you are pregnant, or thinking about becoming pregnant, tell your doctor. Vancomycin should be given during pregnancy, only if clearly needed.

If you are breast-feeding, tell your doctor, as vancomycin passes into breast milk in small amounts and can cause diarrhoea in infants. Your child should be closely monitored for diarrhoea.
Ask your doctor or pharmacist for advice before taking this medicine.

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

3. How to use Vancomycin Mylan

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.

<u>Intravenous administration</u>
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 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 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.

<u>Oral administration</u>
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.

How the treatment will be given
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 vancomycin into your blood and not in the muscle.

Vancomycin 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.

If you use more vancomycin than you should
As this medicine will be given to you while you are in the hospital, it is unlikely that you will be given too much vancomycin. However, tell your doctor or nurse immediately if you have any concerns.

If you have further questions on the use of this product, 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 get any sudden wheeziness, difficulty in breathing, redness on the upper part of the body, rash or itching.

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.

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 generalised exanthematous pustulosis).

Side effects with Vancomycin include:

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 air flow in the upper airway)
- Rash and inflammation of the lining of the mouth, itching, itching 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 muscles
- Fever, chills

Very rare side effects (affect up to 1 in 10,000 people)
- 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
- 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 or, 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 listed in 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 Mylan

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

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

Powder: this medicinal product does not require any special storage conditions.

The stability of the reconstituted solution and further diluted product is stated in the information for health professionals.

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 Vancomycin Mylan contains
The active substance is vancomycin.

Vancomycin 500 mg powder for solution
Each vial contains 500 mg vancomycin (as hydrochloride), equivalent to 500,000 IU.

Vancomycin 1000 mg powder for solution
Each vial contains 1000 mg vancomycin (as hydrochloride), equivalent to 1,000,000 IU.

The other ingredient is hydrochloric acid for pH adjustment.

What Vancomycin looks like and contents of the pack
This medicine is a white to almost white or slightly pink to yellow freeze-dried powder for solution for infusion.
Vial of 500 mg of powder. Box of 1, 5, 10 or 20 vials.
Vial of 1000 mg of powder. Box of 1, 5, 10 or 20 vials.
Not all of the presentations may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
McDermott Laboratories Limited T/A Gerard Laboratories
35/36 Baldoyle Industrial Estate
Grange Road
Dublin 13
Ireland

Manufacturer:
Biologici Italia Laboratories S.r.l.
via Filippo Serpero, Masate, 20060
Italy

Vianex SA Plant C -
16th km Marathonos Ave
Pallini Attiki
15351
Greece

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

Belgium	Vancomycine Viatris 500 mg & 1 g poeder voor oplossing voor infusie
Croatia	Vankomicin Viatris 500 mg & 1000 mg prašak za otopinu za infuziju
Cyprus	Vancomycin Viatris 500 mg & 1 g
Czech Republic	Vancomycin Mylan 500 mg & 1 g, prášek pro přípravu infuzního roztoku
Denmark	Vancomycin "Viatris", 500 mg and 1000 mg, pulver til infusionsvæske, løsning

Greece	Vancomycin / Viatris 500mg & 1g powder for solution for infusion
Ireland	Vancomycin Mylan 500 mg & 1000 mg, powder for solution for infusion
Italy	Vancomicina Mylan
Luxembourg	Vancomycine Viatris 500 mg & 1000 mg poudre pour solution pour perfusion
Norway	Vancomycin "Viatris", 500 mg og 1000 mg, pulver til infusjonsvæske, oppløsning
Romania	Vancomicină Viatris 500 mg & 1000 mg pulbere pentru soluţie perfuzabilă
Slovakia	Vancomycin Mylan 500 mg & 1 g
Slovenia	Vankomicin Mylan 500 mg & 1000 mg prašek za raztopino za infundiranje
Sweden	Vancomycin "Viatris", 500 mg och 1000 mg, pulver till infusionvätska

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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:

Hereafter is an extract from the Summary of Product Characteristics to assist in the administration of Vancomycin. When determining appropriateness of use in a particular patient, the prescriber should be familiar with the Summary of Product Characteristics of the medicinal product.

METHOD OF ADMINISTRATION

Intravenous administration

For intravenous infusion only, not for intramuscular administration.
Intravenous vancomycin is usually administered as an intermittent infusion.

Vancomycin shall only be administered as slow intravenous infusion of at least one hour duration or at a maximum rate of 10 mg/min (whichever is longer) which is sufficiently diluted (at least 100 ml per 500 mg or at least 200 ml per 1000 mg) (see section 4.4).

Patients whose fluid intake must be limited can also receive a solution of 500 mg/50 ml or 1000 mg/100 ml, although the risk of infusion-related undesirable effects can be increased with these higher concentrations.

Continuous vancomycin infusion may be considered, e.g., in patients with unstable vancomycin clearance.
The pH of the reconstituted solution is between 2.8 and 4.5.

Oral administration

The reconstituted and diluted solution may also be used for oral administration. It can be given to the patient to drink after dilution or the diluted material may be administered by a nasogastric tube.

Therapeutic indications for intravenous and oral administration are different. Both administration routes could not be commuted.

HANDLING OF THE MEDICINAL PRODUCT

Preparation of infusion solution

For Vancomycin 500 mg: dissolve the contents of one vial in 10 ml of water for injections.
For Vancomycin 1000 mg: dissolve the contents of one vial in 20 ml of water for injections.
One ml of reconstituted solution contains 50 mg of vancomycin.
After reconstitution this solution should be further diluted. Suitable diluents for further dilution are water for injections, 5% glucose solution or 0.9% sodium chloride solution.

Further dilution is required depending on method of administration:

- Intermittent infusion:

Reconstituted solutions containing 500 mg vancomycin (50 mg/ml) must be diluted with at least 100 ml diluent (5 mg/ml).
Reconstituted solutions containing 1000 mg vancomycin (50 mg/ml) must be diluted with at least 200 ml diluent (5 mg/ml).
The desired dose should be administered by intravenous infusion at a rate of no more than 10 mg/min, over at least 60 minutes.

- Continuous infusion:

1 g or 2 g of vancomycin, corresponding to 2 to 4 vials of reconstituted solution, may be added to a sufficiently large volume of diluent to permit the desired daily dose to be infused over 24 hours.

Stability of the diluted solution:
The chemical and physical stability of the ready-to-use solution (with above mentioned diluents) has been demonstrated for 48 hours at 25°C or up to 96 hours between 2-8°C.
From a microbiological point of view, the prepared solution for infusion should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user. Normally, a 24-hour storage period at 2-8°C may only be exceeded if the solution for infusion has been prepared under controlled and validated aseptic conditions.

Before administration, the reconstituted and diluted solutions should be inspected visually for particule matters and discoloration. Only clear and colourless solution free from particles should be used.

Preparation of the oral solution
After initial reconstitution of the solution in the vial, the quantity of solution to be administered is taken from the vial using a graduated syringe equipped with a needle, transferred to a glass or a baby bottle and diluted in 30 ml of water immediately prior to administration.

Disposal
Vials are for single use only. Unused medicinal products must be discarded.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.