

Vancomycine Mylan

500 mg

Powder for concentrate for solution for infusion or for oral solution

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.
- 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 Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution is and what it is used for,
2. What you need to know before you use Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution,
3. How to use Vancomycine Mylan 500 mg, powder for concentrate for

solution for infusion or for oral solution

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1. What Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution is and what it is used for

ANTIBACTERIAL ANTIBIOTIC OF THE GLYCOPOLYPTIDE FAMILY - ATC code: (J: anti-infective). ATC Code: J01XA01

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 intended for use in a solution for infusion or oral solution.

For intravenous use

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 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,
- meningitis,
- infection in the blood linked to the infections listed above.

For intraperitoneal use:

In patients receiving peritoneal dialysis, vancomycin is used in adults and children for the treatment of peritoneal dialysis infections.

For oral use

Vancomycin can be used orally in adults and children for the treatment of small bowel and colon mucosal infections (pseudo-membranous colitis), caused by *Clostridium difficile* bacteria.

2. What you need to know before you use Vancomycine Mylan 500 mg powder for concentrate for solution for infusion or for oral solution

⚠ Do not use Vancomycine Mylan 500 mg powder for concentrate for solution for infusion or for oral solution

- If you are allergic to vancomycin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:

Talk to your doctor or pharmacist or nurse before using Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution, 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.

Talk to your doctor or hospital pharmacist or nurse during treatment with Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution 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.



The following information is intended for healthcare professionals only

Intravenous administration:

Vancomycin may be diluted with sterile water, 9 mg/mL sodium chloride or 50 mg/mL glucose. Vancomycin is not compatible with solutions of betalactam antibiotics. The risk of precipitation increases with higher concentrations of vancomycin. To prevent precipitation, intravenous cannula and catheters should be flushed with saline between administration of vancomycin and of these antibiotics. Vancomycin solutions must only be diluted to concentrations of 5 mg/mL or less.

The administration of vancomycin by intravitreal injection is not authorised. Precipitation has been observed following intravitreal injection of vancomycin and ceftazidime using separate syringes and needles for the treatment of endophthalmitis. The precipitate in the vitreous body dissolved completely but slowly over a period of 2 months, during which visual acuity also improved.

The powder must be reconstituted and the dilute solution obtained must be diluted further prior to use.

Other medicines and Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution

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

• Medicines potentially harmful to the kidneys

(e.g. aminoglycoside antibiotics, iodine contrast agents, platinum-based chemotherapy agents, methotrexate at high doses, and some antiviral drugs such as pentamidine, foscarnet, aciclovir, ganciclovir, falciclovir, valganciclovir, valganciclovir, ciclosporin or tacrolimus): If you receive vancomycin and other medicines that are potentially harmful to the kidneys simultaneously, this harmful effect can be increased. In such cases, a careful and regular control of the kidney function is necessary.

• Medicines potentially harmful to hearing

(e.g.: aminoglycoside antibiotics, platinum-based chemotherapy agents and some diuretics). If given at the same time as vancomycin, this harmful effect can be increased. In such cases, a careful and regular control of 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, redness of the skin, nettle rash, decreased heart function and itching.

• **Muscle relaxants:** If you take muscle relaxants (e.g. succinylcholine) at the same time, their myorelaxant effect can be intensified or prolonged.

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

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 taking this medicine.

During pregnancy, this medicine may be used if necessary. If you discover that you are pregnant during the course of treatment, see your doctor since he alone can judge whether you need to continue the treatment.

Driving and using machines

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

3. How to use Vancomycine Mylan 500 mg, powder for concentrate for solution for infusion or for oral solution

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 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 old

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 new born 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.

Preparation of the concentrate for solution for infusion

Dissolve the contents of a 500 mg vancomycin vial in 10 mL of sterile water. To prevent precipitation due to the low pH of vancomycin hydrochloride in solution, all intravenous cannula and catheters should be flushed with saline.

Appearance of the infusion concentrate

Clear, colourless solution free from particles.

For storage conditions of the reconstituted medicinal product, see sections 5

NEVER INJECT THE SOLUTION AS IS BUT DILUTE AS FOLLOWS:

-The administration may be carried out as an intermittent infusion, which is the preferred administration route. Add the concentrated solution to 100 mL or 200 mL of solvent. This solution may be administered as a 60-min infusion every 6 hours.

Intraperitoneal administration

Adults and children

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

Oral administration

Adult and children (from 12 to 18 years old)

The recommended dose is 125 mg every 6 hours. In some cases, your doctor may decide to administer a higher daily dose up to 500 mg every 6 hours. The maximum daily dose should not exceed 2 g.

If you have previously had other episodes (of mucosal infection), it is likely that you require a different dose and duration of treatment.

Children

Newborns, infants and children aged less than 12 years old.

The recommended dose is 10 mg per kg of body weight. It is usually administered 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 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.

The administration of vancomycin in your veins takes at least 60 minutes.

Intra-peritoneal use

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

Oral use

For the treatment of gut infections (called pseudomembranous colitis), the drug should be administered as a solution for oral use (you will take the drug 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 take more Vancomycine Mylan 500 mg, powder for concentrate for solution or for oral solution than you should

The symptoms are hearing problems, skin rash or redness in the face, neck, arms or upper portion of the body ("red man syndrome"), and kidney problems.

If you forget to take Vancomycine Mylan 500 mg, powder for concentrate for solution or for oral solution

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

If you stop taking Vancomycine Mylan 500 mg, powder for concentrate for solution or for oral solution

Too low dosage, irregular administration or premature therapy discontinuation can compromise the outcome of the therapy or lead to relapses, which are more difficult to treat. Please follow the instructions of your doctor.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for more information.

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.

Absorption of vancomycin in the digestive tract is negligible. However, if you have inflammatory bowel disease, and especially if you also have kidney problems, side effects such as those described with the infusion administration of vancomycin may occur.

Common side effects (may affect up to 1 to 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 to 100 people)

- temporary or permanent loss of hearing.

Rare side effects (may affect 1 to 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vancomycine Mylan 500 mg powder for concentrate for solution or for oral solution

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. The expiry date refers to the last day of this month.

To store at a temperature below 25 ° C.

The reconstituted solution can be stored for 24 hours at 4 ° C.

When administered orally, the solution reconstituted in drinking water may be stored for 4 days at 4 ° C or 25 ° C.

Do not dispose of any medication in the sewage system or in the household garbage. Ask your pharmacist to eliminate medications that you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vancomycine Mylan 500 mg, powder for concentrate for solution or for oral solution

The active substance is: Vancomycin

Each vial contains 500 mg of vancomycin hydrochloride

equivalent to 500,000 IU of vancomycin.

What Vancomycine Mylan 500 mg looks like and contents of the pack

This medicine is powder for solution for infusion. Box of 1 vial.

This leaflet was last revised in: December 2018.

Health education advice:

Antibiotics are effective in fighting infections caused by bacteria. They are not effective against infections due to viruses.

When your doctor chooses to prescribe an antibiotic, it is because it is appropriate for your current illness.

Despite the action of an antibiotic, some bacteria have the ability to survive and reproduce. This phenomenon is known as resistance: it makes certain antibiotic therapies inactive.

Resistance increases when antibiotics are used inappropriately. You run the risk of encouraging the appearance of resistant bacteria and hence delaying your recovery, or even rendering the antibiotic inactive, if you do not comply appropriately:

- the right dose,
- at the right times,
- over the right period of treatment.

Consequently, to maintain the effectiveness of this medicine

- 1- Only use an antibiotic when it has been prescribed for you by your doctor,
- 2- Follow your doctor's prescription exactly,
- 3- Do not re-use an antibiotic without a medical prescription, even if you think you're fighting an apparently similar disease.

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- or in continuous infusion, add two to four vials of the concentrated solution above to a sufficiently large volume of solvent so that the daily dose desired can be administered slowly, drop wise by IV route, over a 24 hour period.

Parenterally vancomycin shall only 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) which is sufficiently diluted (at least 100 mL per 500 mg or at least 200 mL per 1000 mg).

Patients whose fluid intake must be limited can also receive a solution of 500 mg/50 mL or 1000 mg/100 mL. With these higher concentrations the risk for infusion related side effects can be increased.

Elimination

Vials are for single use only. Unused product must be discarded.

Any unused medicinal product or waste material should be disposed of in

accordance with local requirements.

Administration

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. fatal anaphylactic reaction), treatment with vancomycin should be discontinued immediately and the usual emergency measures have to be started. Patients requiring fluid restriction may be treated with concentrations of up to 10 mg/mL. However, such concentrations involve a greater risk of infusion-related complications. The rate of infusion should under no circumstances exceed 10 mg/min.