

PACKAGE LEAFLET: INFORMATION FOR THE USER

Vancomycin Hydrochloride 500 mg and 1 g Powder for Concentrate for Solution for Infusion Vancomycin hydrochloride

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion is and what it is used for
2. What you need to know before you use Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion
3. How to use Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion
4. Possible side effects
5. How to store Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion
6. Contents of the pack and other information

1. What Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion 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 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 central nervous system
- Infection in the blood linked to the infections listed above.

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. What you need to know before you use Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion

Do not use Vancomycin Hydrochloride

- 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 hospital 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.

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.

Take special care with Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion

- if you have kidney problems
- if you have hearing difficulties

- if you have shown signs of hypersensitivity (severe allergy) to teicoplanin (an antibiotic) in the past

Tell your doctor if any of the above applies to you before this medicine is used.

Special care will be taken if you are elderly or you are due to have a general anaesthetic.

Special care will be taken in prematurely born infants and children.

Taking/using other medicines

Special care is needed if you are taking/using other medicines as some could interact with vancomycin, for example:

- other antibiotics that can affect your kidneys e.g. streptomycin, neomycin, gentamicin, kanamycin, amikacin, tobramycin, arbekacin, paromomycin, polymyxin B, colistin, cephaloridine, ciclosporin
- anti fungals e.g. amphotericin B,
- antibacterials e.g. bacitracin,
- anti-tuberculosis (TB) agents e.g. viomycin,
- platinum-containing anti-cancer agents (e.g. cisplatin, nedaplatin)
- fluorouracil (used in treatment of some cancers)
- water tablets e.g. ethacrynic acid and furosemide
- cholestyramine (a medicine used to treat high levels of fat in the blood or diarrhoea in inflammatory diseases of the gut)
- anaesthetic agents
- muscle relaxants e.g. suxamethonium or vecuronium
- aminophylline (used in asthma treatment)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will decide if you should receive this medicine.

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

Driving and using machines

Do not drive or use machines if you experience any side effect (e.g. dizziness) which may lessen your ability to do so.

3. How to use Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion

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 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.

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 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 administered 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.

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.

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 (may 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 diarrhea, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 676517
Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. How to store Vancomycin Hydrochloride Powder for Concentrate for Solution for infusion

Keep this medicine out of the sight and reach of children

Expiry

This medicine must not be used after the expiry date which is stated on the vial label and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

Keep the vial in the outer carton in order to protect from light, and store at or below 25°C.

Chemical and physical in-use stability has been demonstrated for 4 days at 2-8°C. 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 2-8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

Reconstituted and diluted solutions should be clear. A solution which shows a brown or pink discolouration should be discarded.

6. Contents of the pack and other information

What Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion contains

Each 1 g vial contains vancomycin hydrochloride 1 g equivalent to 1,000,000 IU vancomycin activity.
Each 500 mg vial contains vancomycin hydrochloride 500 mg equivalent to 500,000 IU vancomycin activity.

The other ingredients are:

Sodium hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)

What Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion looks like and contents of the pack

Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion is a white or almost white solid which comes in glass containers called vials.

It may be supplied in packs containing:

- 1 x 500 mg vial
- 1 x 1 g vial

Not all packs may be marketed.

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.

Marketing Authorisation Holder and Manufacturer

Hospira UK Limited, Queensway, Royal Leamington Spa, Warwickshire, CV31 3RW, UK

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The following information is intended for healthcare professionals only:

For single use. Discard any unused contents.

Reconstituted and diluted solutions should be clear and colourless to pale yellow solutions, free from visible particulate matter. A solution which shows a brown or pink discolouration should be discarded.

Preparation of Solution:

At the time of use, add 10 ml of sterile Water for Injections BP to a vial of Vancomycin Hydrochloride 500 mg Powder for Concentrate for Solution for Infusion. Similarly, add 20 ml of sterile Water for Injections BP to a 1 g vial of Vancomycin Hydrochloride 1 g Powder for Concentrate for Solution for Infusion. Vials reconstituted in this manner will give a solution of 50 mg/ml. Further dilution is required depending on method of administration:

- (i) **Intermittent infusion (the preferred method of administration):**

Reconstituted solutions containing 500 mg vancomycin must be diluted with at least 100 ml diluent.
Reconstituted solutions containing 1 g vancomycin must be diluted with at least 200 ml diluent.

Sodium Chloride Intravenous Infusion BP or 5% Dextrose Intravenous Infusion BP are suitable diluents. The desired dose should be administered 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 a possibility of inducing marked hypotension in addition to thrombophlebitis. Rapid administration may also produce flushing and a transient rash over the neck and shoulders.

(ii) Continuous infusion (should only be used when intermittent infusion not feasible):

1 g or 2 g of vancomycin may be added to a sufficiently large volume of Sodium Chloride Intravenous Infusion BP or 5% Dextrose Intravenous Infusion BP to permit the desired dose to be infused over twenty-four hours.

(iii) Oral:

The contents of vials for parenteral administration may be used.

Refer to the Summary of Product Characteristics for further information on the use of vancomycin.

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