

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
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1. What Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion is and what it is used for

Vancomycin is an antibiotic. It is used in potentially life-threatening infections, caused by Gram-positive organisms, which will respond to vancomycin but which would not respond to other, less toxic antibiotics.

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

Do not use Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion

- if you have shown signs of hypersensitivity (severe allergy) to vancomycin in the past
- Tell your doctor if the above applies to you before this medicine is used.

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

This medicine will be dissolved in Water for Injections and further diluted in e.g. sodium chloride intravenous infusion, before it is given to you. It will usually be given as a slow infusion via a drip into a vein. The desired dose should be administered by intravenous infusion at a rate of no more than 10 mg/min or it may be given as a continuous infusion over 24 hours.

Vancomycin can also be given orally (by mouth) to treat certain infections of the bowel. It may also be given via a tube through the nose. The taste of vancomycin is extremely unpleasant.

Dose

Your doctor will work out the correct dose of vancomycin for you and how often it must be given.

The dose of medicine given to you will depend on your age, the infection you have, how well your kidneys are working, if you have poor hearing and any other medicines you may be taking. Your doctor will tell how well your kidneys are working using blood or urine samples.

It will take at least 2 or 3 days for you to respond to vancomycin. The length of the course of treatment depends on the infection being treated and may last a number of weeks.

To minimise the risk of a low blood pressure reaction, your blood pressure will be monitored during the infusion.

During treatment you will undergo blood tests, be asked to provide urine samples and possibly have hearing tests to look for signs of toxic side effects. Blood tests will also be used during treatment to check the level of vancomycin in your blood.

If you are given too much or too little Vancomycin Hydrochloride Powder for Concentrate for Solution for Infusion

This medicine will be given to you by a doctor or nurse. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, vancomycin can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- chest pain
- hearing loss or ringing in your ears
- blistery rash or scaling of the skin
- fast heart beat, palpitations, breathlessness or wheezing
- dizziness or feeling faint
- severe diarrhoea with blood in it

These are serious side effects. You may need urgent medical attention.

If any of the following happen, tell your doctor as soon as possible:

- flushing over the upper body
- widespread skin rash which may be itchy
- fever, chills, shivering
- muscle spasms or cramp
- tingling or numbness (e.g. pins and needles)
- a change in the amount or colour of urine
- fluid retention
- pain, swelling, redness or itching at the injection site
- feeling sick or vomiting
- mouth ulcers

- diarrhoea
- abdominal pain
- jaundice (yellow colouring of the skin or white part of the eyes)

Vancomycin may lead to changes in your blood cells, liver and kidney function. Your doctor may take blood samples to check for these.

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.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in 11/2015

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.