Package leaflet: Information for the user

Vancomycin Hydrochloride 500 mg and 1 g Powder for Concentrate 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 Infusion is and what it is used for
2. What you need to know before you use Vancomycin Hydrochloride Powder for Concentrate for Infusion
3. How to use Vancomycin Hydrochloride Powder for Concentrate for Infusion
4. Possible side effects
5. How to store Vancomycin Hydrochloride Powder for Concentrate for Infusion
6. Contents of the pack and other information

1. What Vancomycin Hydrochloride Powder for Concentrate 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 Infusion

Do not use Vancomycin Hydrochloride Powder for Concentrate 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 Infusion
• if you have kidney problems
• if you have hearing difficulties

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

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

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, polymyxin B and colistin
• water tablets e.g. ethaerynic acid and frusemide
• cholestyramine (a medicine used to treat high levels of fat in the blood or diarrhoea in inflammatory diseases of the gut)

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 breastfeeding. 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 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 infusion will last at least 60 minutes and be repeated during the day 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.

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 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
• blistered rash or scaling of the skin
• fast heart beat, palpitations or breathlessness
• dizziness or feeling faint

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

If any of the following happen, tell your doctor as soon as possible:
• widespread skin rash which may be itchy
• fever, chills, shivering
• muscle spasms
• a change in the amount or colour of urine
• fluid retention
• pain, swelling, redness or itching at the injection site
• feeling sick or vomiting
• diarrhoea

Vancomycin may lead to changes in your blood cells 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

UK
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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 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.

The reconstituted solution should be used immediately, however, if this is not possible it can be stored for up to 4 days in a refrigerator, provided it has been prepared in a way to exclude microbial contamination.

6. Contents of the pack and other information

What Vancomycin Hydrochloride Powder for Concentrate for Infusion contains

The active substance is vancomycin. After reconstitution each millilitre (ml) of solution contains 50 milligrams (mg) of vancomycin.

There are no other ingredients.

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

Vancomycin Hydrochloride Powder for Concentrate 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

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The following information is intended for healthcare professionals only:

For single use. Discard any unused contents.

Preparation of Solution:

At the time of use, add 10 ml of sterile Water for Injections BP to a 500 mg vial of Vancomycin Hydrochloride 500 mg Powder for Concentrate 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 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 B.P. or 5% Dextrose Intravenous Infusion B.P. 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 B.P. or 5% Dextrose Intravenous Infusion B.P. to permit the desired dose to be infused over twenty-four hours.

(iii) **Oral Administration:**

The contents of vials for parenteral administration may be used.