Vancomycin AN Powder for Injection

contains the active ingredient vancomycin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have benefits and risks. Your doctor has weighed the risks of you taking Vancomycin AN against the benefits they expect it will have on you. If you have any concerns about taking this medicine, talk to your doctor or pharmacist. Keep this leaflet with your medicine. You may need to read it again.

What Vancomycin AN is used for

Vancomycin AN is used to treat serious or severe bacterial infections. Your doctor, however, may have prescribed Vancomycin AN for another purpose. Ask your doctor if you have any questions about why Vancomycin AN has been prescribed for you. Vancomycin AN is a broad-spectrum antibiotic and belongs to a glycopeptide group of antibiotics. This medicine works by stopping bacteria from growing and reducing the bacteria's ability to function. Vancomycin AN will not work against infections caused by viruses, such as colds or flu. Vancomycin AN is available only with a doctor's prescription.

Before you are given Vancomycin AN intravenous infusion

When you must not be given it

You have ever had an allergic reaction to medicines containing the active ingredient, vancomycin. Some of the symptoms of an allergic reaction may include rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.

Before you are given it

- You have, or have ever had, any other health problems or medical conditions, especially kidney damage, hearing problems, blood problems or inflammatory bowel disorders;
- You are pregnant or plan to become pregnant. Your doctor will discuss the risks and benefits of taking Vancomycin AN when pregnant;
- You are breastfeeding or wish to breastfeed. Your doctor will discuss the risks and benefits of taking Vancomycin AN when breastfeeding;
- 4. You are allergic to any other medicines or other substances such as foods, preservatives or dyes. If you have not told your doctor or pharmacist about any of the above, tell them before you start taking or are given Vancomycin ACT.
- The packaging is torn or shows any signs of tampering;
- The use by date or expiry date printed on the pack has passed. If this medicine is used after the expiry date has passed, it may not work as well.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines may be affected by Vancomycin AN or may affect how well Vancomycin AN works.

These include:

- Some other medicines used to treat infections, such as amicacin, amphotericin, colistin, gentamycin, neomycin and tobramycin;
- Cisplatin, an anticancer medicine;
- Some fluid tablets (diuretics) such as ethacrynic acid and frusemide;
- Anaesthetic agents;
- Cholestyramine, a powder taken to lower cholesterol levels;

• Medicine used to relax muscles. These medicines may be affected by vancomycin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when using Vancomycin AN or may have more information on medicines to be careful with or avoid while you are being given this medicine.

How to take Vancomycin ACT

Your doctor will tell you how much to take and when to take it. Take Vancomycin AN exactly as directed by your doctor. This may differ from the information contained in this leaflet.

How much to take

Vancomycin AN is administered intravenously under the supervision of a doctor or a nurse. The usual adult daily intravenous dose of vancomycin hydrochloride is either 500 mg every 6 hours or 1000 mg every 12 hours (when in solution). Each dose should be administered at no more than 10 mg/minute or over a period of at least 60 minutes, whichever is the longer. Infusion-related events are related to both the concentration and the rate of administration of vancomycin hydrochloride. For children the dose varies depending on their age, weight and how sick they are. Your doctor will adjust the amount or frequency of your doses according to the infection being treated and the severity of your condition. If you do not understand the instructions provided, ask your doctor or pharmacist for help.

How long to take Vancomycin Hydrochloride for Intravenous Infusion for

Your doctor will tell you how long you will be treated with Vancomycin AN. Check with your doctor if you are not sure how long you should be taking Vancomycin AN.

While you are taking Vancomycin ACT

Things you must do

If you are being given Vancomycin AN for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

Tell your doctor if you become pregnant while taking Vancomycin AN. If you are

about to start taking a new medicine, tell your doctor or pharmacist that you are taking Vancomycin AN.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Vancomycin AN.

If you are going to have surgery, tell the surgeon and anaesthetist that you are being given this medicine.

Things to be careful of

Be careful driving or operating machinery until you know how vancomycin affects you. This medicine may cause dizziness in some people. If you drink alcohol, dizziness may be worse.

Things you must not do

Do not use Vancomycin AN to treat any other complaints unless your doctor says so. Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Vancomycin AN. Vancomycin AN helps most people with bacterial infections, but it may have unwanted side effects in some people. If you are over 65 years of age you may have an increased chance of getting side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

While you are taking Vancomycin AN

Tell your doctor if you experience any of the following and they worry you: nausea (feeling sick), diarrhoea, vomiting or mild diarrhoea or rashes.

Tell your doctor immediately if you notice any of the following, as you may need urgent medical care:

- allergic reaction including shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rashes, itching or hives on the skin, pain and muscle spasm;
- a change in the amount or frequency of urine passed;
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin;
- hearing loss, dizziness, ringing in the ears, loss of balance;
- chest pains or palpitations;
- redness around the needle site of injection or infusion;
- severe diarrhoea;
- fast or irregular heartbeat;
- chills or fever, which may be accompanied by shivering.

The above list includes serious side effects which may require urgent medical attention. Serious side effects are rare.

After you have finished being given Vancomycin ACT

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after treatment with vancomycin:

- Severe abdominal cramps or stomach cramps;
- Watery or severe diarrhoea which may also be bloody;
- Fever, in combination with one or both of the above.

These are serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, these side effects are rare.

Tell your doctor if you notice anything that is making you feel unwell while you are being given, or soon after you have finished being given Vancomycin AN, even if it is not on this list.

After using Vancomycin AN

Storage

Vancomycin AN will be kept on the ward or in the pharmacy in a cool dry place below 25°C.

To reduce microbiological hazard, infusion should be commenced as soon as practicable after reconstitution/preparation. If storage is necessary, the solution should be held at $2 - 8^{\circ}$ C for not more than 24 hours.

Disposal

Unused or out dated Vancomycin AN should be disposed of by the standard procedures of the pharmacy at the institution where it is administered.

Product Description

What it looks like

Vancomycin AN is available as a sterile, white to light brown powder in a glass vial. When reconstituted with sterile water for injections, it forms a clear solution. Vancomycin AN is available in two strengths: 500 mg (grey flip-off cap) and 1000 mg (green flip-off cap).

Ingredients

The active ingredient in Vancomycin AN is vancomycin hydrochloride.

Australian registration numbers

Vancomycin AN 500 mg: AUST R 118999 Vancomycin AN 1000 mg: AUST R 119000

Supplier

Vancomycin AN is supplied by: Medis Pharma Pty Ltd 1002/53 Walker Street North Sydney NSW 2060 Australia **Date of Preparation:** May 2016