#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about Vancomycin Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given vancomycin against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

## Keep this leaflet.

You may need to read it again.

# What Vancomycin Sandoz is used for

This medicine is used to treat severe infections caused by bacteria in different parts of the body.

This medicine belongs to a group of medicines called glycopeptide antibiotics.

# Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

# Before you are given Vancomycin Sandoz

### When you must not be given it You must not be given Vancomycin Sandoz if you have an allergy to:

- · vancomycin, the active ingredient
- the inactive ingredient, disodium edetate.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

# If you are not sure whether you should be given this medicine, talk to your doctor.

You should not be given Vancomycin Sandoz if the packaging is torn or shows signs of tampering.

You should not be given Vancomycin Sandoz after the expiry date on the pack.

## Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

## Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- hearing problems
- inflammatory bowel disorders.

# Tell your doctor if you are pregnant or intend to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you are given Vancomycin Sandoz.

### Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Vancomycin Sandoz may interfere with each other.

These include:

- some other medicines used to treat infections, such as amphotericin and colistin
- · cisplatin, an anticancer medicine
- some fluid tablets (diuretics), such as ethacrynic acid and frusemide
- cholestyramine, a powder taken to lower cholesterol levels
- suxamethonium or vecuronium, medicines 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 and pharmacist have more information on medicines to be careful with or avoid while you are being given this medicine.

## How Vancomycin Sandoz is given

#### How much is given

Your doctor will decide what dose of vancomycin you will receive and how long you will receive it for. This depends on your condition and other factors, such as your weight and kidney function.

### How it is given

Vancomycin Sandoz is usually given as a slow injection into a vein (intravenous drip). It must take at least 60 minutes for the injection to be given. Vancomycin Sandoz must only be given by a doctor or nurse.

Sometimes, vancomycin is taken orally (swallowed). Vancomycin Sandoz may be diluted with water and flavoured with syrup (as it has an unpleasant taste) and given as a drink

# If you are given too much (overdose)

As Vancomycin Sandoz is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose

However, if you experience severe side effects after being given vancomycin, tell your doctor or nurse immediately.

# While you are being treated with Vancomycin Sandoz

### Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given vancomycin.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant soon after being given vancomycin, tell your doctor.

### 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 this occurs, do not drive, operate machinery or do anything else that could be dangerous. If you drink alcohol, dizziness may be worse.

#### Side effects

# Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with vancomycin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

# Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

Tell your doctor or nurse if you notice any of the following and they worry you:

- · irritation at the injection site
- · nausea, vomiting or mild diarrhoea
- · dizziness.

These side effects are usually mild.

# Tell your doctor or nurse immediately if you notice any of the following:

- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- severe abdominal cramps or stomach cramps
- flushing of the upper body or pain and muscle spasm of the chest and back
- · fast or irregular heart beat
- ringing in the ears or difficulty hearing
- · blood in the urine.

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

## After finishing it

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

- severe abdominal cramps or stomach cramps
- watery and 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. Do not take any diarrhoea medicine without first checking with your doctor.

# Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients. Some of these side effects (for example changes in kidney function) can only be found when your doctor does tests from time to time to check your progress.

## After using Vancomycin Sandoz

#### Storage

Vancomycin Sandoz will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

### Product description

### What it looks like

Vancomycin Sandoz comes as a white to off white powder in a glass vial. When reconstituted with sterile water for injection, it forms a clear solution.

Vancomycin Sandoz is available in vials containing 500 mg vancomycin (500,000 IU of vancomycin activity) in packs of 1 and 10 vials or in vials containing 1 g vancomycin (1,000,000 IU of vancomycin activity) in packs of 1 vial.

## Ingredients

Active ingredients - vancomycin hydrochloride.

Inactive ingredients - disodium edetate.

## Supplier

Sandoz Pty Ltd ABN 60 075 449 553 54 Waterloo Road Macquarie Park, NSW 2113 Australia

Tel: 1800 634 500

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## $Australian\ Register\ Number(s)$

500 mg powder for injection - AUST R 100021 (vial)

1 g powder for injection - AUST R 100011 (vial)