

Vancomycin Alphapharm

contains the active ingredient vancomycin hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Vancomycin Alphapharm.

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 taking Vancomycin Alphapharm against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Vancomycin Alphapharm is used for

Vancomycin Alphapharm is used to treat severe infections of the body caused by bacteria, such as:

- severe staphylococcal infections
- endocarditis, an infection that causes inflammation of the lining of the heart
- osteomyelitis (bone infection)
- pneumonia (lung infection)
- septicaemia (infection of the blood)
- skin and skin structure infections
- infections in the intestines.

It belongs to a group of medicines called glycopeptide antibiotics. It works by killing the bacteria that are causing the infection.

Vancomycin Alphapharm may be used alone, or in combination with other medicines, to treat your condition.

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 Alphapharm

When you must not be given it

You must not be given Vancomycin Alphapharm if you have an allergy to:

- any medicine containing vancomycin
- any of the ingredients listed at the end of this leaflet.

Some of the 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.

Before you start to take it

Tell your doctor if you are allergic 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, including hearing loss

- inflammatory bowel disorders.

Tell your doctor if you have an allergy to teicoplanin, an antibiotic used to treat serious infections.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell him/her before you are given Vancomycin hydrochloride.

Taking other medicines

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

Some medicines and Vancomycin Alphapharm may interfere with each other. These include:

- antibiotics, such as neomycin, gentamicin, amikacin, bacitracin, tobramycin, colistin or viomycin
- antifungal medicines, such as amphotericin B (amphotericin)
- cisplatin, an anticancer medicine

- fluid tablets (diuretics), such as etacrynic acid and furosemide (frusemide)
- anaesthetic agents
- colestyramine, a powder taken to lower cholesterol levels
- suxamethonium or vecuronium, medicines used to relax muscles.

These medicines may be affected by Vancomycin Alphapharm or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Vancomycin Alphapharm 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 how well your kidneys are working.

How it is given

Vancomycin Alphapharm will always be prepared and given to you by a doctor or healthcare professional.

It is usually given as a slow injection into a vein (intravenous drip).

It can be given as an oral solution to treat serious infections of the bowel and colon (large bowel).

Your doctor or healthcare professional may use a flavoured syrup to improve the taste.

How often will it be given

For most infections, Vancomycin Alphapharm is given in divided doses throughout the day.

Your doctor will decide for how long you will be given Vancomycin Alphapharm. This will depend on the severity of the infection being treated.

Overdose

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Vancomycin Alphapharm. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being treated with Vancomycin Alphapharm

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 Alphapharm.

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.

Your doctor may do some tests from time to time to prevent unwanted side effects.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things to be careful of

Be careful driving or operating machinery until you know how Vancomycin Alphapharm affects you.

This medicine may cause dizziness in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are taking Vancomycin Alphapharm.

This medicine helps most people with serious infections but it may have unwanted side effects in some people.

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:

- stomach ache
- chills
- pain, inflammation or flaking at the injection site
- nausea (feeling sick) or vomiting
- mild diarrhoea

- Difficulty hearing, dizziness or a spinning sensation

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor 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
- fever, sore throat or mouth ulcers
- flushing of the upper body
- pain or muscle spasm of the chest and back
- fast or irregular heartbeat
- buzzing, hissing, whistling, ringing or other persistent noise in the ear
- other infections
- bleeding or bruising more easily than normal
- skin blister and bleeding in the lips, eyes, mouth, nose and genitals.

The above list includes serious side effects that may require urgent medical attention.

Hearing loss has occurred in some patients being given Vancomycin Alphapharm. Most of these have occurred in

patients who have pre-existing conditions such as kidney disease or partial hearing loss.

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

Other side effects not listed above may also occur in some people.

After you have received 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 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.

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 being given Vancomycin Alphapharm

Storage

Store vials prior to reconstitution in a cool dry place, where the temperature stays below 25°C. Protect from light.

Vancomycin Alphapharm will be stored in the pharmacy or on the ward.

This medicine is for single use only. Any unused solution should be discarded.

Do not store Vancomycin Alphapharm or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Vancomycin Alphapharm is a white to almost white or slightly pink or yellow powder in a glass vial.

When reconstituted with sterile water for injection or glucose, it forms a clear solution.

Ingredients

The active ingredient is vancomycin hydrochloride.

Hydrochloric acid may be added to adjust pH.

Vancomycin Alphapharm does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Vancomycin Alphapharm is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Vancomycin Alphapharm 500 mg (as hydrochloride) powder
for Injection Vial AUST R 153438

Vancomycin Alphapharm 1 g (as hydrochloride) powder for
Injection Vial AUST R 153439

This leaflet was prepared in

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