

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

**PrVANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP
(Vancomycin Hydrochloride)
500 mg/vial, 1 g/vial, 5 g/vial and 10 g/vial
Sterile lyophilized powder for solution**

Read this carefully before you start taking VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP.

What is VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP used for?

Vancomycin is used to treat bacterial infections in many different parts of the body such as:

- Heart
- Bone
- Lung
- Blood
- Skin and muscle

Vancomycin is typically used for serious infections for which other medicines may not work.

Antibacterial drugs like VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP, treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP should be used exactly as directed. Misuse or overuse of VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP could lead to the growth of bacteria that will not be killed by VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP (resistance). This means that VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP may not work for you in the future. Do not share your medicine.

How does VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP work?

Vancomycin hydrochloride is in a family of medications called glycopeptide antibiotics. It works by preventing the growth of certain types of bacteria.

What are the ingredients in VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP?

Medical ingredients: Vancomycin hydrochloride

Non-medical ingredients: Sodium hydroxide and hydrochloric acid

VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP comes in the following dosage forms:

VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP comes as a sterile powder. It is supplied in vial. Each vial may contain:

- 500 mg of vancomycin (as vancomycin hydrochloride)
- 1 g of vancomycin (as vancomycin hydrochloride)
- 5 g of vancomycin (as vancomycin hydrochloride)
- 10 g of vancomycin (as vancomycin hydrochloride)

Do not use VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP if:

- You are allergic to vancomycin hydrochloride.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP. Talk about any health conditions or problems you may have, including if you:

- Have kidney problems
- Have hearing problems
- Are pregnant or planning to become pregnant
- Are breast feeding

Other warnings you should know about VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP:

While you are using VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP

- **Elderly:** VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP may cause damage to your hearing and kidneys (see the “Serious side effects and what to do about them” table below). These side effects may be more likely to occur in elderly patients. During your treatment your healthcare professional may require that you do blood, kidneys and hearing tests.
- If you are going to have surgery, including dental surgery, tell your healthcare professional that you are receiving vancomycin. Vancomycin may affect other medicines used during surgery.
- If you develop severe diarrhea (very loose or watery stool), tell your healthcare professional right away. Diarrhea may mean that you have a serious condition affecting your bowel (colitis). You may need urgent medical care. Do not try to treat loose stools without first checking with your healthcare professional (see the “Serious side effects and what to do about them” table below).
- Stop taking vancomycin at the first sign of a skin rash and call your healthcare professional. Skin rash may be a sign of a more serious reaction to vancomycin (see the “Serious side effects and what to do about them” table below).
- **Driving and using machines:** This medicine may cause dizziness in some people. If this occurs, do not drive, use machines or do anything else that could be dangerous.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP:

- Other medications in the antibiotics family such as:
 - aminoglycoside antibiotics such as amikacin, gentamicin, kanamycin, paromomycin, tobramycin etc.
 - cephaloridine (not marketed in Canada)
 - polymixin B
 - colistin
 - viomycin (not marketed in Canada)
- Cisplatin, a medicine used to treat cancer
- Medications given during surgery to relax the muscles (neuromuscular blocking agents)

Always keep a list of your medicines and show it to your healthcare professional when you get a new medicine. It is important that your healthcare professional reviews all medications and supplements you are taking before prescribing VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP.

How to take VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP:

- VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP is usually injected slowly into the vein over a period of at least 60 minutes. You may receive it at the hospital, or clinic.
- Under certain circumstances, VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP may also be given orally to treat colitis (inflammation of the intestine caused by certain bacteria) that may occur after antibiotic treatment.

Usual dose:

- Your healthcare professional will work out the right amount (dose) of medicine for you. The dose will depend on:
 - the medical problem for which you are using vancomycin
 - your weight, age
 - how well your kidneys are working and other factors.
- Your healthcare professional will explain to you the dosing instructions for VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP (amount of medicine to take, number of doses to take each day, the time allowed between doses, and how long you need take this medicine).
- Ask your healthcare professional if you have any questions about the dosing instructions.

Overdose:

Your healthcare professional is trained to recognize the symptoms of an overdose, and deal with its symptoms.

If you think you, or a person you are caring for, have taken too much VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have missed a dose of medication, call your healthcare professional to find out what to do.

What are possible side effects from using VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP?

These are not all the possible side effects you may feel when taking VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP. If you experience any side effects not listed here, contact your healthcare professional.

See also the “To help avoid side effects and ensure proper use...” section.

Check with your healthcare professional if any of these side effects persist or become troublesome:

- Headache.
- Shortness of breath.
- Sick to stomach.
- Rash, irritation, pain, redness or swelling where the shot is given.
- Tiredness.
- Vomiting.
- Fever.
- Diarrhea.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Unknown frequency			
Reactions that may occur during your infusion or soon after your infusion is completed: <ul style="list-style-type: none"> • Chills, • itching or skin irritation, nausea, shortness of breath, wheezing, rash on the face, neck, trunk, and arms • flushing of the skin over the neck and shoulder ("red neck") 		✓	
Serious life-threatening skin reactions (Stevens-Johnson syndrome, Toxic Epidermal Necrolysis, Drug Reaction/Rash with Eosinophilia and Systemic Symptoms (DRESS)): <ul style="list-style-type: none"> • unexplained widespread skin pain • flu-like symptoms (fever, sore mouth and throat, cough, fatigue, burning eyes etc.) • followed by a painful red or purplish rash that spreads and blisters on mouth, nose, eyes and genital • shedding of your skin within days after blisters form • swelling of the face or swollen glands in the neck, armpits or groin • yellowing of your skin or eye • dark urine, light-colored bowel movements; • severe nausea or vomiting; stomach pain 			✓
Rare			
Allergic reactions: <ul style="list-style-type: none"> • severe rash, hives, itching • swelling of face, lips, mouth, throat or tongue • wheezing • tightness in the chest or throat • difficulty breathing or talking 			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Kidney problems: <ul style="list-style-type: none"> • unable to pass urine • change in the amount of urine you pass • Pain in urinating, blood in the urine • Tiredness, nausea, vomiting • Swollen hands and feet 			✓
Hearing problems: <ul style="list-style-type: none"> • dizziness, problems with balance • vertigo (spinning sensation) • ringing in the ears (is a potential warning sign of hearing loss) • change in hearing • temporary or permanent hearing loss 			✓
Blood problems (neutropenia, agranulocytosis) (usually found when your doctor orders tests) <ul style="list-style-type: none"> • more likely to develop infections, sore throat, fever, chills, and other signs of infection 			✓
Bowel infection (Clostridium difficile colitis): May happen 2 or more months after your treatment <ul style="list-style-type: none"> • diarrhea that does not go away (bloody or watery) with or without: <ul style="list-style-type: none"> ○ fever ○ stomach cramps 			✓
Vasculitis (inflammation of your blood vessels): <ul style="list-style-type: none"> • fever • headache • fatigue • weight loss • general aches and pains • night sweats • rash • nerve problems, such as numbness or weakness 		✓	

If you have troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage

- Store VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP powder between 20°C and 25°C.
- Reconstituted solutions and further diluted infusion mixtures should be used within 24 hours if kept at room temperature or within 96 hours if stored under refrigeration (5°C).
- Most of the time, VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP will be given in a hospital.
- Keep out of reach and sight of children.

If you want more information about VANCOMYCIN HYDROCHLORIDE FOR INJECTION, USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.ca, or by calling 1-800-463-6001.

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