

# iMedix: Your Personal Health Advisor.

## Valcyte

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  - **Storage:**
  - **Market Price:**
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## Description

Side Effects Diarrhea, upset stomach, dizziness, drowsiness, unsteadiness, or shaking (tremors) may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if you have any serious side effects, including: mental/mood changes (such as confusion, hallucinations), signs of kidney problems (such as change in the amount of urine), seizures. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. How long does it take for this medicine to take effect? The onset of action for Valcyte, as measured by the reduction in viral load or improvement in clinical symptoms, can vary depending on the severity of the infection and the patient's immune status. Clinical improvements or significant reductions in CMV viral load can be observed within 1 to 2 weeks after initiating therapy, but it may take longer for the full antiviral effects to be realized. How long do the effects of this medicine last? The duration of Valcyte's effects depends on the course of treatment, which is typically determined by the patient's response to therapy and the condition being treated. For the prevention of CMV disease in transplant recipients, treatment durations of up to 100 to 200 days are common. The antiviral effects of Valcyte persist as long as therapeutic levels of the drug are maintained in the bloodstream. Is it safe to consume alcohol while taking this medicine? While there is no specific contraindication against consuming alcohol while taking Valcyte, it is generally advisable to avoid or limit alcohol intake. Both alcohol and Valcyte can be hepatotoxic, and consuming alcohol may increase the risk of liver damage, particularly in individuals with pre-existing liver conditions or those taking other hepatotoxic drugs. Is this a habit forming medicine? Valcyte is not considered habit-forming. It does not have psychoactive properties or potential for abuse or dependence. It is used strictly for its antiviral activity against CMV infections under medical supervision. Can this medicine be taken during pregnancy? Valcyte is classified as FDA Pregnancy Category C, indicating that animal reproduction studies have shown an adverse effect on the fetus, and there are no adequate and well-controlled studies in humans. However, the potential

benefits of using Valcyte in pregnant women may warrant use of the drug despite potential risks. Valcyte should only be used during pregnancy if the potential benefits justify the potential risk to the fetus, and it should be used with caution after a thorough risk-benefit assessment by a healthcare provider. Can this medicine be taken while breast-feeding? It is not known whether valganciclovir, the active metabolite of Valcyte, is excreted in human breast milk. Due to the potential for serious adverse reactions in nursing infants from Valcyte, a decision should be made whether to discontinue breastfeeding or to discontinue the drug, taking into account the importance of the drug to the mother's health. The use of Valcyte in nursing mothers should be approached with caution, and alternative feeding options may need to be considered.

**Uses** Valganciclovir is an anti-viral drug. It is changed in the body to the active form of the drug called ganciclovir. It is used to prevent disease caused by a virus called cytomegalovirus (CMV) in people who have received organ transplants. CMV disease can lead to serious infections in the body, including an infection in the eye, called CMV retinitis, that can cause blindness. Valganciclovir works by slowing the growth of the CMV virus. It helps prevent the spread of infection to other areas of the body. Valganciclovir is also used to treat CMV retinitis in people with advanced HIV disease (AIDS). This medication helps control CMV retinitis and decrease the risk of blindness. Valganciclovir is not a cure for CMV disease. Some people may have worsening CMV retinitis even with treatment. It is important to have your eyes checked regularly by your doctor.

**How to use Valcyte** Read the Patient Information Leaflet if available from your pharmacist before you start taking valganciclovir and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth with food as directed by your doctor, usually 1 to 2 times a day. Swallow the tablets whole. Do not crush or break the tablets. If you are using the liquid form of this medication, shake the bottle well before each dose. Carefully measure the dose using the special measuring device provided. Do not use a household spoon because you may not get the correct dose. Wash your hands well after handling this drug. Avoid contact with broken/crushed tablets and the liquid form of this medication on your skin, in your mucous membranes and eyes, and avoid breathing in the dust from the tablets. If contact should occur, wash the area thoroughly with soap and water. If this medication gets in your eyes, rinse them thoroughly with plain water. The dosage and length of treatment is based on your medical condition (especially kidney function). In children, the dosage is also based on their body size. The doctor should keep track of your child's height and weight to make sure that the dose is right for them. This medication works best when the amount of drug in your body is kept at a constant level. Take this drug at evenly spaced intervals. To help you remember, take it at the same time(s) each day. Continue taking this medication exactly as prescribed by your doctor. Do not change your dose or stop taking it even for a short time unless directed to do so by your doctor. Changing or skipping your dose without approval from your doctor may increase the risk of side effects or make the infection worse. Do not take ganciclovir instead of valganciclovir on your own without consulting your doctor or pharmacist. The effects and the dosages of ganciclovir and valganciclovir are not equal. Tell your doctor if your condition worsens (such as worsening vision).

**Warnings** Valganciclovir turns into the drug ganciclovir inside your body. Ganciclovir can decrease bone marrow function. This serious, possibly life-threatening side effect may lead to a low number of blood cells such as red cells, white cells, and platelets. This effect can cause anemia, decrease your body's ability to fight an infection, and cause bleeding problems. Your doctor will check the results of your blood tests and adjust your treatment to reduce your risk for these side effects. Get medical help right away if you develop signs of anemia (such as unusual tiredness, fast breathing, pale skin, fast heartbeat), signs of infection (such as sore throat that doesn't go away, fever, chills, cough), and signs of bleeding (such as easy bruising/bleeding, nose bleeds, bleeding gums, bloody/black/tarry stools, vomit that looks like coffee grounds). Ganciclovir may reduce fertility in men and women. It may also harm an unborn baby. Talk to your doctor for more details. Ganciclovir has caused tumors in lab animals. Although there is no information in humans, valganciclovir should be considered cancer-causing (carcinogenic).

**Interactions** Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Some products that may interact with this drug include: didanosine, imipenem/cilastatin, maribavir. You may be taking other drugs that decrease bone marrow function and lower your number of blood cells (such as cancer chemotherapy, trimethoprim/sulfamethoxazole, zidovudine) or other drugs that may cause kidney problems (such as

cyclosporine). Your doctor or pharmacist will monitor you closely and adjust your medications to decrease your risk of serious side effects. Valganciclovir is very similar to ganciclovir. Do not use medications containing ganciclovir while using valganciclovir. Precautions Before taking valganciclovir, tell your doctor or pharmacist if you are allergic to it; or to ganciclovir or acyclovir; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney problems (such as kidney dialysis), a low number of blood cells (red or white blood cells, platelets), radiation treatment. This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Valganciclovir can make you more likely to get infections or may make current infections worse. Stay away from anyone who has an infection that may easily spread (such as chickenpox, COVID-19, measles, flu). Talk to your doctor if you have been exposed to an infection or for more details. Tell your health care professional that you are using valganciclovir before having any immunizations/vaccinations. Avoid contact with people who have recently received live vaccines (such as flu vaccine inhaled through the nose). To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports. Older adults may be at greater risk for kidney problems while using this drug. Women who are pregnant or who may become pregnant should not handle this medication. During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Discuss the risks and benefits with your doctor. Women of childbearing age should have a pregnancy test before starting this medication. To prevent pregnancy, men with female partners should always use effective barrier protection (such as latex or polyurethane condoms) during all sexual activity during treatment and for at least 90 days after stopping the medication. Women of childbearing age who are taking valganciclovir should use reliable forms of birth control (such as birth control pills and condoms) during treatment and for at least 30 days after stopping the medication. Consult your doctor for more details. It is unknown if this medication passes into breast milk. Because of the possible risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding. If you have HIV, do not breast-feed because breast milk can transmit HIV. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Do not share this medication with others. Lab and/or medical tests (such as complete blood count, kidney function, eye exams) should be done while you are taking this medication. Keep all medical and lab appointments. Consult your doctor for more details. If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store the tablets at room temperature away from light and moisture. Do not store in the bathroom. Store the liquid form of this medication in the refrigerator. Do not freeze. The medication expires 49 days after it was prepared by the pharmacy. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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## Side Effects

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## Uses

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## Interactions

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## Other Details

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