

Patient Information

VALCYTE® (valganciclovir hydrochloride) Tablets

VALCYTE® (valganciclovir hydrochloride) for Oral Solution

R_x only

Read the Patient Information that comes with Valcyte before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor.

What is the most important information I should know about Valcyte?

- **Valcyte can affect your blood cells and bone marrow causing serious and life-threatening problems.** Valcyte can lower the amount of your white blood cells, red blood cells, and platelets. Your doctor may do regular blood tests to check your blood cells while you are taking Valcyte. Based on these tests, your doctor may change your dose or tell you to stop taking Valcyte.
- **Valcyte may cause cancer.** Valcyte causes cancer in animals. It is not known if Valcyte causes cancer in people.
- **Valcyte may cause birth defects.** Valcyte causes birth defects in animals. It is not known if Valcyte causes birth defects in people. **If you are pregnant, talk to your doctor before taking Valcyte.**
 - **Tell your doctor right away if you become pregnant while taking Valcyte.**
 - **If you are a female who can become pregnant, you should use effective birth control during treatment with Valcyte and for at least 30 days after treatment.**
 - **Men should use a condom during treatment with Valcyte, and for at least 90 days after treatment, if their female sexual partner can become pregnant.** Talk to your doctor if you have questions about birth control.
- **Valcyte may lower the amount of sperm in a man's body and cause fertility problems.**
- **Valcyte can affect your kidney, including serious problems such as kidney failure.** Your doctor may do regular blood tests to check your kidney function while you are taking Valcyte. Your doctor may adjust your dose based on these tests.
- **Valcyte changes into the medicine ganciclovir once it is in your body.** Ganciclovir is also the active ingredient in Cytovene®-IV and ganciclovir capsules. Do not take ganciclovir capsules or Cytovene-IV if you are taking Valcyte. The dose of medicine in Valcyte tablets and ganciclovir capsules is different. **One tablet of Valcyte has more medicine than one capsule of ganciclovir. This means that one Valcyte tablet cannot be substituted for one ganciclovir capsule. You could overdose and become very sick if Valcyte is taken with ganciclovir capsules or Cytovene-IV.** Talk to your doctor or pharmacist if you have questions about your medicine.

What is Valcyte?

Valcyte is an “antiviral” medicine.

In adults, Valcyte tablets are used:

- to treat cytomegalovirus (CMV) retinitis in people who have acquired immunodeficiency syndrome (AIDS). When CMV virus infects the eyes, it is called CMV retinitis. If CMV retinitis is left untreated, it can cause blindness.
- to prevent cytomegalovirus (CMV) disease in people who have received a **heart, kidney, or kidney-pancreas** transplant and who have a high risk for getting CMV disease.

In children (4 months to 16 years of age) Valcyte tablets or oral solution are used:

- to prevent cytomegalovirus (CMV) disease in children who have received a **heart or kidney** transplant and have a high risk for getting CMV disease.

Valcyte is not for use in adults or children who have received a liver transplant.

It is not known if Valcyte is safe and effective:

- to prevent CMV disease in people who have had other types of organ transplants such as lung or intestine.
- to prevent CMV disease in children under 4 months of age who receive an organ transplant.
- to treat CMV disease that a baby might be born with (congenital CMV disease)
- in adults older than age 65.

Valcyte does not cure CMV retinitis. You may still get retinitis or worsening of retinitis during or after treatment with Valcyte. It is important to stay under a doctor's care and have your eyes checked regularly.

Who should not take Valcyte?

Do not take Valcyte tablets if you are receiving hemodialysis. The use of ganciclovir capsules rather than Valcyte tablets is recommended.

Do not take Valcyte if you are allergic to any of its ingredients or if you have ever had a serious allergic reaction to ganciclovir capsules or Cytovene-IV. Symptoms of an allergic reaction to Valcyte may include: sudden trouble breathing, wheezing, hives all over your body, swelling around your mouth, or feeling anxious.

See the [end of this leaflet](#) for a list of the ingredients in Valcyte.

What should I tell my doctor before taking Valcyte?

Before taking Valcyte, tell your doctor if you:

- have kidney problems. Your doctor may give you a lower dose of Valcyte, or check you more often if you are taking Valcyte.
- have blood cell problems
- are having radiation treatment
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Valcyte causes birth defects in an unborn baby. **Tell your doctor right away if you become pregnant while taking Valcyte. See [“What is the most important information I should know about Valcyte?”](#)**
- are breast-feeding or plan to breast-feed. It is not known if Valcyte passes into your milk and if it may harm your baby. You should not breast-feed if you are HIV-positive because of the chance of passing the HIV virus to your baby through your milk.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Valcyte and other medicines may affect each other and cause serious side effects. Especially tell your doctor if you take:

- didanosine (Videx[®])
- zidovudine (Retrovir[®], Trizivir, Combivir)
- probenecid (Col-Probenecid, Probenecid and Colchicine)
- mycophenolate mofetil (CellCept[®])

How should I take Valcyte?

- Take Valcyte exactly as your doctor prescribes it. Your dose of Valcyte will depend on your medical condition.
- Adults should only take Valcyte tablets. Children may take either Valcyte tablets or oral solution.
- Take Valcyte with food.

- Do not break or crush Valcyte tablets. Avoid contact with your skin or eyes. If you come in contact with the contents of the tablet or oral solution, wash your skin well with soap and water or rinse your eyes well with plain water.
- If your child is prescribed Valcyte for oral solution, your pharmacist will give you dosing dispensers to measure your dose of Valcyte for oral solution. To be sure you receive the prescribed dose, it is important to use the dispenser provided to you. Be sure to read, and that you understand, and follow the instructions below on how to take Valcyte for oral solution and how to use the dispenser. Ask your pharmacist if you have any questions. If you lose or damage your dispensers and cannot use them, contact your pharmacist.
- If you miss a dose of Valcyte, take the missed dose as soon as you remember. Then, take the next dose at the usual scheduled time. However, if it is almost time for your next dose, **do not take the missed dose.**
- Do not let your Valcyte run out. The amount of virus in your blood may increase if your medicine is stopped, even for a short time.
- If you take too much Valcyte, call your local poison control center or emergency room right away. You may need treatment in a hospital.
- Do not substitute Valcyte tablets for ganciclovir capsules. Talk to your doctor, nurse or pharmacist if you have questions about your medicine.

What should I avoid while taking Valcyte?

- **Valcyte can cause seizures, sleepiness, dizziness, unsteady movements, and confusion. You should not drive a car or operate other dangerous machinery until you know how Valcyte affects you.**

What are the possible side effects of Valcyte?

Valcyte may cause serious side effects, including:

- See [“What is the most important information I should know about Valcyte?”](#)

Common side effects of Valcyte in adults and children include:

- diarrhea
- nausea, vomiting
- fever
- shaky movements (tremors)
- low white cell, red cell and platelet cell counts in blood tests
- rejection of the transplanted organ (graft)

Other common side effects in children include:

- constipation
- high blood pressure
- cough and colds

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Valcyte. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Valcyte?

- Store Valcyte tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Store Valcyte for oral solution in the refrigerator between 36°F to 46°F (2°C to 8°C), for no longer than 49 days. Do not freeze.
- Do not keep medicine that is out of date or that you no longer need.
- **Keep Valcyte and all medicines out of the reach of children.**

General information about Valcyte

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Valcyte for a condition for which it was not prescribed. Do not give Valcyte to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about Valcyte. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Valcyte that is written for health professionals.

For more information about Valcyte go to www.VALCYTE.com or call 1-888-835-2555.

What are the ingredients in Valcyte?

Active Ingredient: valganciclovir hydrochloride

Inactive Ingredients for Tablets: microcrystalline cellulose, povidone K-30, crospovidone, and stearic acid. The film-coating applied to the tablets contains Opadry Pink®.

Inactive Ingredients for Oral Solution: sodium benzoate, fumaric acid, povidone K-30, sodium saccharin, mannitol and tutti-frutti flavoring.

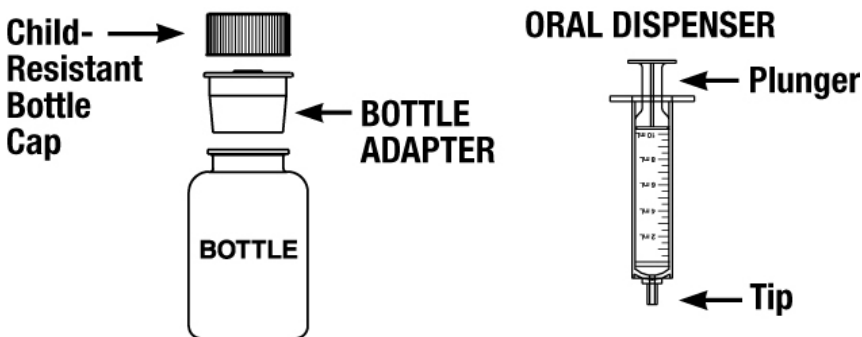
Patient Instructions for Use

How do I give Valcyte for oral solution?

Your pharmacist will mix Valcyte for oral solution for you.

Be sure that you read, and that you understand and follow these instructions carefully to ensure proper dosing of the oral solution. To take a dose of Valcyte for oral solution, you will need the bottle of medicine and an oral dispenser. See **Figure 1** below.

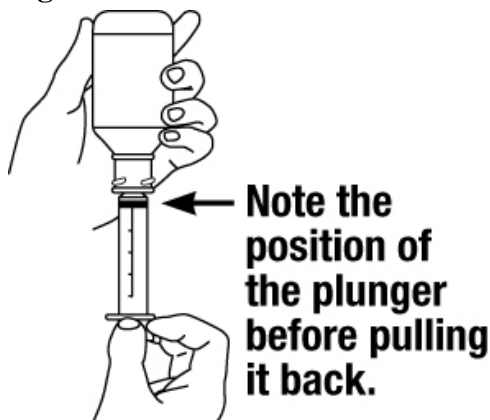
Figure 1:



- Shake closed bottle well for about 5 seconds before each use.
- Remove the child-resistant bottle cap.
- Before inserting the tip of the oral dispenser into bottle adapter, push the plunger completely down toward the tip of the oral dispenser.
- Insert tip firmly into opening of the bottle adapter.

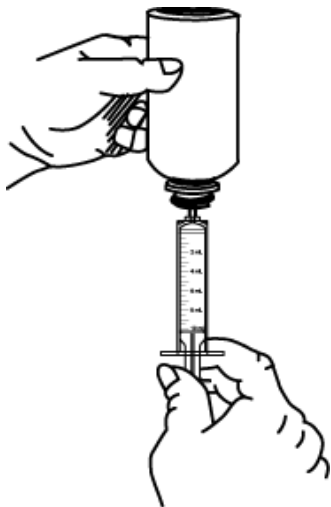
Turn the entire unit (bottle and oral dispenser) upside down (see **Figure 2**).

Figure 2:



- Make sure the dosing dispenser stays connected to the bottle. Pull the plunger down slowly until the prescribed amount of medicine is withdrawn into the oral dispenser (see **Figure 3**).

Figure 3:



- Turn the entire unit right side up and remove the oral dispenser slowly from the bottle.
- Give the dose of medicine directly into mouth and swallow. Do not mix with any liquid before giving the dose.
- Close the bottle with child-resistant bottle cap after each use.
- After taking your medicine, take apart (disassemble) the oral dispenser right away and rinse under running tap water. Then air dry before next use.

Avoid skin contact with Valcyte for oral solution. If you come in contact with Valcyte for oral solution, wash the area well with soap and water.

Do not use Valcyte for oral solution after the expiration date on the bottle.

Call your pharmacist if your oral dispenser is lost or damaged, and they will tell you how to continue to take your medicine.

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