

## Patient Information

### VALCYTE (valganciclovir hydrochloride) Tablets

### VALCYTE (valganciclovir hydrochloride) for Oral Solution

#### R<sub>x</sub> only

Read the Patient Information that comes with Valcyte (VAL-site) 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 healthcare provider.

#### 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. Valcyte should not be used during pregnancy. **Tell your doctor right away if you get pregnant while taking Valcyte. If you can get 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 partner can get 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 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 used in:

##### Adults:

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

##### Children (4 months to 16 years of age):

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

Valcyte may:

- slow the growth of CMV virus in your body. CMV is an infection caused by a herpes virus called cytomegalovirus. If CMV retinitis isn't treated, it can cause blindness. Valcyte may protect your eyesight from damage due to CMV disease. CMV can also infect other parts of the body.
- prevent CMV disease for up to 6 months after **heart, kidney, or kidney-pancreas** transplant. Valcyte may prevent CMV virus from spreading into healthy cells.

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

The safety and efficacy of Valcyte have not been established in pediatric patients younger than 4 months of age.

The safety and efficacy of Valcyte have not been studied in adults older than age 65.

### **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 reaction to ganciclovir capsules or Cytovene-IV.** See the end of this leaflet for a list of the ingredients in Valcyte.

In addition, Valcyte is not for use in prevention of CMV disease in adults or children who have received a liver transplant. More research is needed before Valcyte can be recommended for use in the prevention of CMV disease in organ transplant patients other than those indicated (such as lung transplant patients).

### **Before taking Valcyte, tell your doctor:**

- **if you are pregnant or plan to become pregnant.** Valcyte may cause birth defects. (See **“What is the most important information I should know about Valcyte?”**)
- **if you are breast-feeding.** 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.
- **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.
- **if you have blood cell problems**
- **if you are having radiation treatment**
- **about all the medicines you take,** including prescription and non-prescription medicines, vitamins and herbal supplements. **Do not take ganciclovir capsules or Cytovene-IV if you are taking Valcyte.** Valcyte and other medicines may affect each other. These interactions may cause serious problems. The following medicines may need dose changes if you are also taking Valcyte:
  - Videx (didanosine, ddI)
  - Retrovir (zidovudine, ZDV, AZT)
  - Probenecid

Tell your doctor if you take medicines such as chemotherapy medicines that can lower your bone marrow function.

### **How should I take Valcyte?**

- Valcyte is taken as a tablet for adults and either an oral solution or tablet for children. Take Valcyte exactly as your doctor prescribes it.
- If your doctor prescribes you Valcyte for oral solution, your pharmacist will give you dosing dispensers to measure your dose of Valcyte for oral solution. In order to be sure you receive the recommended dose, it is important to use the dispenser provided to you. Review 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 healthcare professional or pharmacist.

- Your dose of Valcyte will depend on your medical condition. If you have kidney problems or you are over age 65, your doctor may give you a lower dose of Valcyte.
  - the usual dose for adults to get active CMV retinitis under control (induction therapy) is two 450 mg tablets twice a day for 21 days.
  - the usual dose for adults to help keep CMV retinitis under control (maintenance therapy) is two 450 mg tablets once a day.
  - the usual dose to prevent CMV in adults who have had a **heart, kidney, or kidney-pancreas** transplant is two 450 mg tablets once a day starting within 10 days of transplant and continuing until 100 days after the transplant.
- Take Valcyte with food.
- Do not break or crush Valcyte tablets.
- 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. Adult patients should use Valcyte tablets, not Valcyte for oral solution. Talk to your doctor, nurse or pharmacist if you have questions about your medicine.

### What should I avoid while taking Valcyte?

- **Do not get pregnant.** Valcyte causes birth defects in animals. It is not known if Valcyte causes birth defects in people. Valcyte should not be used during pregnancy. **Tell your doctor right away if you get pregnant while taking Valcyte. If you can get 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 partner can get 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.
- **Do not breast-feed.** Valcyte 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.
- **Do not drive a car or operate other dangerous machinery until you know how Valcyte affects you.** Valcyte can cause seizures, sleepiness, dizziness, unsteady movements, and confusion.
- **Do not break or crush Valcyte tablets.** Avoid contact with broken Valcyte tablets on your skin, mucous membranes or eyes. If contact occurs, wash your skin well with soap and water or rinse your eyes well with plain water.

### What are the possible side effects of Valcyte?

See “**What is the most important information I should know about Valcyte?**” for details on the most serious side effects. **Valcyte can also cause the following serious side effects:**

- **kidney problems.** Valcyte may affect your kidney function. Your doctor may do regular blood tests called serum creatinine levels to check your kidney function while you are taking Valcyte.
- **brain and nerve problems.** Valcyte may cause seizures, sleepiness, dizziness, unsteady movements, and confusion.

**Common side effects** of Valcyte include diarrhea, nausea, vomiting, stomach pain, fever, headache, shaky movements (tremors), graft rejection, swelling of the legs, constipation, back pain, trouble sleeping, and high blood pressure.

Common changes in blood tests for people taking Valcyte include low white blood cells (neutropenia or leukopenia), low red blood cells (anemia), increased blood creatinine levels, increased calcium in the blood, and abnormal liver function.

Talk to your doctor about side effects that bother you or that won't go away.

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

### **How do I store Valcyte?**

- Valcyte tablets should be stored at room temperature, 59° to 86°F (15° to 30°C).
- Valcyte for oral solution should be stored under refrigeration at 36° to 46°F (2° to 8°C), for no longer than 49 days. Do not freeze.
- **Keep Valcyte and all medicines out of the reach of children.** Do not keep medicine that is out of date or that you no longer need. Dispose of unused medicines through community take-back disposal programs when available or place Valcyte in an unrecognizable, closed container in the household trash.

### **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. Information about Valcyte is also available at 1-888-835-2555 (toll-free).

### **What are the ingredients in Valcyte?**

**Active Ingredient:** valganciclovir HCl

**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.

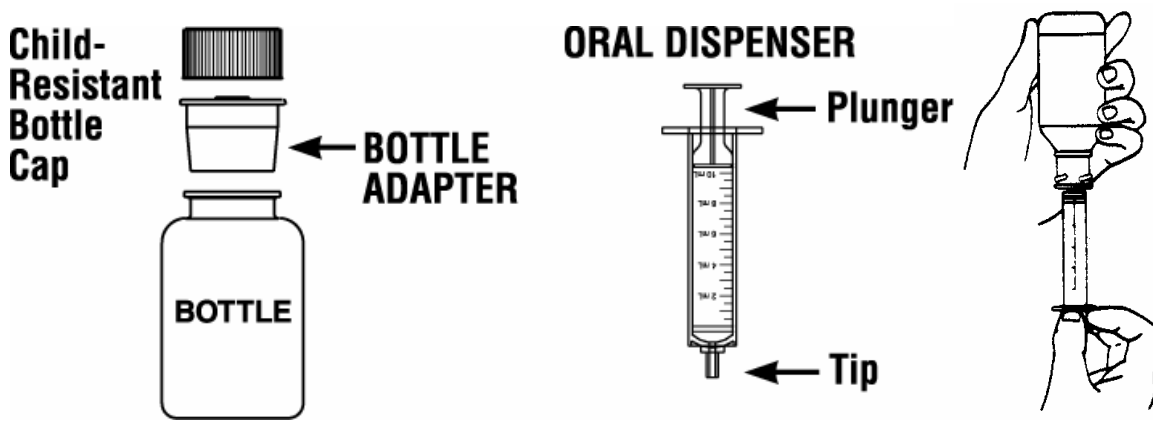
## **Dosing Instructions for Patients**

### **How do I take Valcyte for oral solution?**

Valcyte for oral solution will be prepared by the pharmacist prior to dispensing the medication to you.

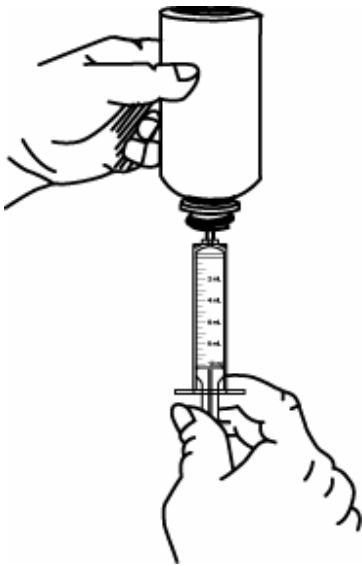
Please follow instructions carefully to ensure proper dosing of the oral solution.

**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 1).
- Pull the plunger out slowly until the desired amount of medication is withdrawn into the oral dispenser (see Figure 2). The 18 mL (900 mg) dose is obtained by filling the dispenser twice, once to the 8 mL (400 mg) graduation, and a second fill to the 10 mL (500 mg) graduation.

**Figure 2:**



- Turn the entire unit right side up and remove the oral dispenser slowly from the bottle.
- Dispense directly into mouth and swallow. Do not mix with any liquid prior to dispensing.
- Close bottle with child-resistant bottle cap after each use.
- Immediately after receiving your medication, disassemble oral dispenser, rinse under running tap water and air dry prior to next use.

Care should be taken to avoid contact of the skin with the solution. If such contact occurs, wash thoroughly with soap and water.

Do not use the solution after the expiration date.

Contact your doctor or pharmacist if your oral dispenser is lost or damaged, and they will advise you on how to continue to take your medication.

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