

## Patient Information

### Valganciclovir (val gan SYE kloe veer) tablets

#### What is the most important information I should know about valganciclovir tablets?

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

#### What are valganciclovir tablets?

Valganciclovir tablet is a prescription antiviral medicine.

#### In adults, valganciclovir 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, valganciclovir tablets are used:

- to prevent cytomegalovirus (CMV) disease in children 4 month to 16 years of age who have received a heart transplant and have a high risk for getting CMV disease.

**Pediatric use information for pediatric kidney transplant patients ages 4 months to 16 years and for pediatric heart transplant patients ages 1 to less than 4 months is approved for Roche Palo Alto LLC's VALCYTE (valganciclovir hydrochloride) tablets. However, due to Roche Palo Alto LLC's marketing exclusivity rights, this drug product is not labeled with that pediatric information.**

**Valganciclovir tablets do not cure CMV retinitis.** You may still get retinitis or worsening of retinitis during or after treatment with valganciclovir tablets. It is important to stay under a healthcare provider's care and have your eyes checked every 4 to 6 weeks during treatment with valganciclovir tablets.

#### Who should not take valganciclovir tablets?

**Do not take valganciclovir tablets 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 valganciclovir tablets 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 valganciclovir tablets.

#### What should I tell my healthcare provider before taking valganciclovir tablets?

**Before taking valganciclovir tablets, tell your healthcare provider if you:**

- have kidney problems. Your doctor may give you a lower dose of valganciclovir tablets, or check you more often if you are taking valganciclovir tablets.
- are receiving hemodialysis.
- 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 valganciclovir tablets causes birth defects in an unborn baby.
- **Tell your healthcare provider right away if you become pregnant while taking valganciclovir tablets. See "What is the most important information I should know about valganciclovir tablets?"**

- are breastfeeding or plan to breastfeed. It is not known if valganciclovir passes into your breast milk. You should not breastfeed if you take valganciclovir tablets.
  - You should not breastfeed if you have Human Immunodeficiency Virus (HIV-1) because of the risk of passing HIV-1 to your baby.
  - Talk to your healthcare provider about the best way to feed your baby.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins and herbal supplements.

Valganciclovir tablets and other medicines may affect each other and cause serious side effects. Keep a list of your medicines to show your healthcare provider and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with valganciclovir tablets.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take valganciclovir tablets with other medicines.

#### How should I take valganciclovir tablets?

- Take valganciclovir tablets exactly as your healthcare provider tells you. Your dose of valganciclovir tablets will depend on your medical condition.
- Adults should only take valganciclovir tablets. Children may take either valganciclovir tablets or oral solution.
- Take valganciclovir tablets with food.
- Do not break or crush valganciclovir 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 you miss a dose of valganciclovir tablets, 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 valganciclovir tablets 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 valganciclovir tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

Talk to your healthcare provider, nurse or pharmacist if you have questions about your medicine.

#### What should I avoid while taking valganciclovir tablets?

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

#### What are the possible side effects of valganciclovir tablets?

Valganciclovir tablets may cause serious side effects, including:

See "**What is the most important information I should know about valganciclovir tablets?**"

**Common side effects of valganciclovir tablets in adults and children include:**

- diarrhea
- nausea, vomiting
- low white cell, red cell and platelet cell counts in blood tests

- fever
- shaky movements (tremors)
- rejection of the transplanted organ (graft)

#### Other common side effects in children include:

- headache
- high blood pressure
- upper respiratory tract infection
- urinary tract infection

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

These are not all the possible side effects of valganciclovir tablets. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### How should I store valganciclovir tablets?

- Store valganciclovir tablets at 25°C; excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.]
- Do not keep valganciclovir tablets that is out of date or that you no longer need.
- **Keep valganciclovir tablets and all medicines out of the reach of children.**

#### General information about the safe and effective use of valganciclovir tablets

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflet. Do not use valganciclovir tablets for a condition for which it was not prescribed. Do not give valganciclovir tablets to other people, even if they have the same symptoms you have. It may harm them.

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

#### What are the ingredients in valganciclovir tablets?

**Active Ingredient:** valganciclovir hydrochloride, USP

**Inactive Ingredients:** crospovidone, microcrystalline cellulose, povidone and stearic acid. The tablets are coated with Opadry Pink which contains hypromellose, iron oxide red, polyethylene glycol, polysorbate 80 and titanium dioxide.

This Patient Information has been approved by the U.S. Food and Drug Administration



Manufactured for:  
Camber Pharmaceuticals, Inc.  
Piscataway, NJ 08854

By: **HETERO™**  
Hetero Labs Limited, Unit V, Polepally,  
Jadcherla, Mahabubnagar - 509 301, India.

Revised: March 2016

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