

PATIENT INFORMATION

Valganciclovir Tablets USP (val" gan sye' kloevir)

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

Valganciclovir can cause serious side effects, including:

- **Blood and bone marrow problems.** Valganciclovir can affect the bone marrow lowering the amount of your white blood cells, red blood cells, and platelets and may cause serious and life-threatening problems.
- **Kidney failure.** Kidney failure may happen in people who are elderly, people who take valganciclovir with certain other medicines, or people who are not adequately hydrated.
- **Fertility problems.** Valganciclovir may lower sperm count in males and cause fertility problems. Valganciclovir may also cause fertility problems in women. Talk to your healthcare provider if this is a concern for you.
- **Birth defects.** Valganciclovir causes birth defects in animals. It is not known if valganciclovir causes birth defects in people. If you are a female who can become pregnant, you should use effective birth control during treatment with valganciclovir and for at least 30 days after treatment. **If you are pregnant, talk to your healthcare provider before starting treatment with valganciclovir. If you are a female who can become pregnant, you should have a pregnancy test done before starting valganciclovir.**
 - Tell your healthcare provider right away if you become pregnant during treatment with valganciclovir.
 - Males should use condoms during treatment with valganciclovir, 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.
- **Cancer.** Valganciclovir causes cancer in animals and may potentially cause cancer in people.

Your healthcare provider will do regular blood tests during treatment with valganciclovir to check you for side effects. Your healthcare provider may change your dose or stop treatment with valganciclovir if you have serious side effects.

What is valganciclovir?

Valganciclovir 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 not treated, it can cause blindness.
- to prevent CMV disease in people who have received a **kidney, heart, or kidney-pancreas** transplant and who have a high risk for getting CMV disease.

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

In children, valganciclovir tablets or oral solution are used:

- to prevent CMV disease in children 4 months to 16 years of age who have received a **kidney** transplant and have a high risk for getting CMV disease.
- to prevent CMV disease in children 1 month to 16 years of age who have received a **heart** transplant and have a high risk for getting CMV disease. It is not known if valganciclovir is safe and effective in children for prevention of CMV disease in liver transplant, in kidney transplant in infants less than 4 months of age, in heart transplant in infants less than 1 month of age, in children with AIDS who have CMV retinitis, and in infants with congenital CMV infection.

Do not take valganciclovir if you have had a serious allergic reaction to valganciclovir, ganciclovir or any of the ingredients of valganciclovir. See the end of this leaflet for a list of the ingredients in valganciclovir.

Before you take valganciclovir, tell your healthcare provider about all of your medical conditions, including if you:

- have low blood cell counts
- have kidney problems
- are receiving hemodialysis
- are receiving radiation treatment
- are pregnant or plan to become pregnant. See "What is the most important information I should know about valganciclovir?"
- are breastfeeding or plan to breastfeed. It is not known if valganciclovir passes into your milk. You should not breastfeed if you take valganciclovir.
 - 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 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.
- **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 with other medicines.

How should I take valganciclovir?

- Take valganciclovir exactly as your healthcare provider tells you. Your dose of valganciclovir will depend on your medical condition.
- Adults should only take valganciclovir tablets. Children may take either valganciclovir tablets or oral solution.
- Take valganciclovir 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, wash your skin well with soap and water or rinse your eyes well with plain water.
- If you take too much valganciclovir tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid during treatment with valganciclovir?

Valganciclovir can cause seizures, dizziness, and confusion. You should not drive a car or operate machinery until you know how valganciclovir affects you.

What are the possible side effects of valganciclovir?

Valganciclovir may cause serious side effects, including:

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

The most common side effects of valganciclovir in adults include:

- diarrhea
- fever
- fatigue
- nausea
- shaky movements (tremors)
- low white cell, red cell and platelet cell counts in blood tests
- headache
- sleeplessness
- urinary tract infection
- vomiting

The most common side effects of valganciclovir in children include:

- diarrhea
- fever
- upper respiratory tract infection
- urinary tract infection
- vomiting
- low white blood cell counts in blood tests
- headache

These are not all the possible side effects of valganciclovir

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 valganciclovir tablets?

- Store valganciclovir tablets at room temperature between, 20°C-25°C (68°F-77°F).
- Do not keep valganciclovir tablets that are 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

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use valganciclovir for a condition for which it was not prescribed. Do not give valganciclovir to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about valganciclovir that is written for health professionals.

What are the ingredients in valganciclovir tablets?

Active Ingredient: valganciclovir hydrochloride

Inactive Ingredients for Tablets: crospovidone, magnesium stearate, microcrystalline cellulose and povidone. The film-coating applied to the tablets contains hypromellose, iron oxide red, polyethylene glycol, polysorbate and titanium dioxide.

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

For more information, call 1-888-375-3784.

Rx Only

Manufactured by
Dr. Reddy's Laboratories Limited
Bachupally – 500 090 INDIA

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Dispense with Patient Information Sheet available at:
www.drreddys.com/pi/valganciclovirtabs.pdf

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