

PATIENT INFORMATION

Valganciclovir (val-gan-SYE-kloe-ver) hydrochloride for oral solution

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 lifethreatening 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 breast 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 or oral solution, wash your skin well with soap and water or rinse your eyes well with plain water.
- If your child is prescribed valganciclovir for oral solution, your pharmacist will give you oral dosing dispensers to measure your child’s dose of valganciclovir for oral solution. To be sure you receive the prescribed dose, it is important to use the dispenser provided to you. See the detailed Instructions for Use below for information about how to take valganciclovir for oral solution.
Ask your pharmacist if you have any questions. If you lose or damage your oral dispensers and cannot use them, contact your pharmacist.
- If you take too much valganciclovir, 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 | • low white cell, red cell and platelet cell counts in blood tests |
| • fever | • headache |
| • fatigue | • sleeplessness |
| • nausea | • urinary tract infection |
| • shaky movements (tremors) | • vomiting |

The most common side effects of valganciclovir in children include:

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

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?

- Store valganciclovir for oral solution in the refrigerator between 36° to 46°F (2° to 8°C), for no longer than 49 days.

- Do not freeze.
- Do not keep valganciclovir that is out of date or that you no longer need.

Keep valganciclovir 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?

Active ingredient: valganciclovir hydrochloride

Inactive ingredients for oral solution: are mannitol, sodium benzoate, sucralose, tartaric acid and tutti-frutti flavoring.

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Manufactured by:

Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

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For more information about valganciclovir, please contact Granules Pharmaceuticals Inc. at 1-877-770-3183.

Instructions for Use
Valganciclovir (val-gan-SYE-kloe-ver) Hydrochloride for Oral Solution

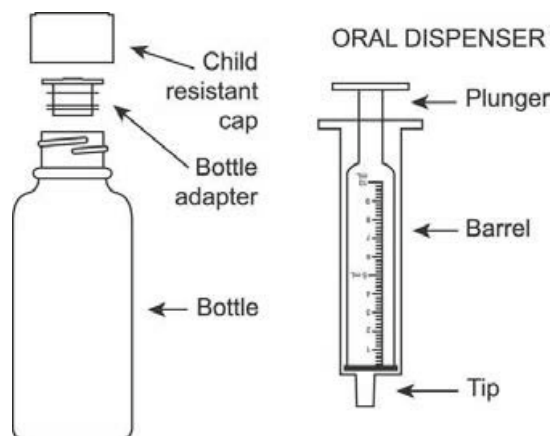
Be sure that you read, and that you understand and follow these instructions carefully to ensure proper dosing of the oral solution.

Important:

- Avoid contact with your skin or eyes. If you come in contact with the contents of the oral solution, wash your skin well with soap and water or rinse your eyes well with plain water.
- Do not use valganciclovir hydrochloride for oral solution after the discard date on the bottle.
- Always use the oral dispenser provided to give or take a dose of valganciclovir hydrochloride for oral solution.
- Call your pharmacist if your oral dispenser is lost or damaged, and they will tell you how to continue to give or take a dose of valganciclovir hydrochloride for oral solution.
- Ask your healthcare provider or pharmacist to show you how to measure your prescribed dose.

To take a dose of valganciclovir hydrochloride for oral solution, you will need the bottle of medicine and an oral dispenser provided with the medicine (see **Figure 1**). Your pharmacist inserts the bottle adapter in the valganciclovir hydrochloride for oral solution bottle.

Figure 1



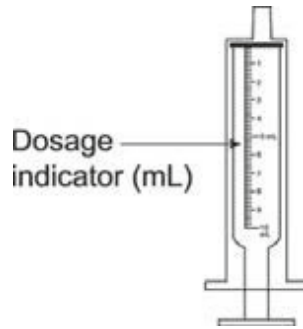
Step 1: With the child-resistant cap on the bottle, shake the bottle well for about 5 seconds before each use.



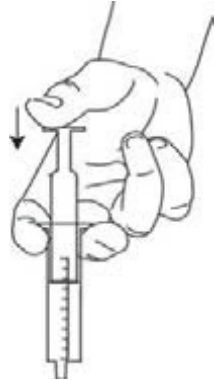
Step 2: Open the bottle by pressing downward firmly on the child-resistant cap and turning it counterclockwise. **Do not throw away the child-resistant cap.**



Step 3: Check the dose in milliliters (mL) as prescribed by your healthcare provider. Find this number on the oral dispenser.



Step 4: Push the plunger down toward the tip of the oral dispenser.



Step 5: With the bottle in an upright position, insert the oral dispenser into the bottle adapter opening until firmly in place.



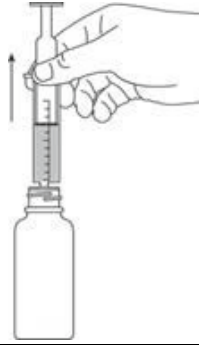
Step 6: Carefully turn the bottle upside down with the oral dispenser in place. Pull the plunger to withdraw the prescribed dose.

If you see air bubbles in the oral dispenser, fully push in the plunger so that the oral solution flows back into the bottle.

Then withdraw your prescribed dose of valganciclovir hydrochloride for oral solution.

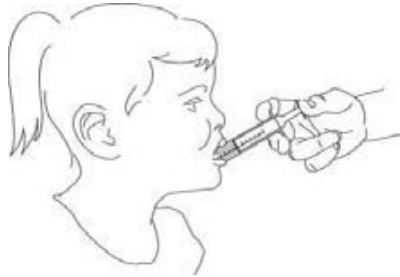


Step 7: Leave the oral dispenser in the bottle adapter and turn the bottle to an upright position. Slowly remove the oral dispenser from the bottle adapter.



Steps 8: Give or take the dose of valganciclovir hydrochloride for oral solution.

- Place the tip of the oral dispenser in the mouth.
- Slowly push down the oral dispenser plunger until the oral dispenser is empty.



Step 9: Put the child-resistant cap back on the bottle. Return the bottle back to the refrigerator.

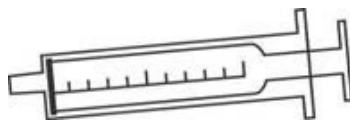


Step 10: Rinse the oral dispenser with tap water after each use.

- Remove the plunger from the oral dispenser barrel by pulling the plunger all the way out of the barrel.
- Rinse the oral dispenser barrel and plunger with water and let them air dry.



- When the oral dispenser barrel and plunger are dry, put the plunger back into the oral dispenser barrel for the next use.



Do not throw away the oral dispenser

How should I store valganciclovir hydrochloride for oral solution?

- Store solution in the refrigerator at 36° to 46°F (2° to 8°C) for no longer than 49 days.
- Do not freeze.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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