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Valganciclovir

pronounced as (val gan sye' kloh veer)

IMPORTANT WARNING:

Valganciclovir may lower the number of red blood cells, white blood cells, and platelets in your body, causing serious and life-threatening problems. Tell your doctor if you have or have ever had a lower number of red blood cells, white blood cells, or platelets; or other blood or bleeding problems. Tell your doctor if you have ever developed blood problems as a side effect of a medication similar to valganciclovir such as ganciclovir (Cytovene). Also, tell your doctor and pharmacist if you are taking or have taken any of the following medications: chemotherapy medications such as doxorubicin (Doxil), vinblastine, and vincristine; dapsone; flucytosine (Ancobon); hydroxyurea (Droxia, Siklos); immunosuppressants such as cyclosporine (Gengraf, Neoral, Sandimmune) and tacrolimus (Prograf); medications to treat human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) including didanosine (Videx) or zidovudine (Retrovir, AZT); pentamidine (NebuPent, Pentam); trimethoprim/sulfamethoxazole (Bactrim, Septra); or if you have received or are receiving radiation (X-ray) therapy. If you experience any of the following symptoms, call your doctor immediately: excessive tiredness; weakness; pale skin; dizziness; confusion; fast heartbeat; difficulty falling asleep or staying asleep; shortness of breath; unusual bleeding or bruising; or a sore throat, fever, chills, cough, or other signs of infection.

Valganciclovir may harm the fetus. Do not take valganciclovir if you are pregnant or plan to become pregnant. If you are female, you will need to take a pregnancy test before you start treatment and use effective birth control during your treatment and for 30 days after your final dose. If you are male and your partner can become pregnant, you should use a condom while taking this medication and for 90 days after your final dose. Talk to your doctor if you have questions about birth control. If you become pregnant while taking valganciclovir, call your doctor immediately.

Valganciclovir may temporarily or permanently decrease fertility in men and women. Talk to your doctor about the risks of taking valganciclovir.

Laboratory animals who were given valganciclovir developed cancer. It is not known if valganciclovir increases the risk of cancer in humans.

Keep all appointments with your doctor, eye doctor, and the laboratory. Your doctor(s) may order regular eye exams and certain tests to check your body's response to valganciclovir.

Talk to your doctor about the risks of taking valganciclovir.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient and read it carefully before you start taking this medication and each time you get a refill.

Why is this medication prescribed?

Valganciclovir is used to treat cytomegalovirus (CMV) retinitis (eye infection that can cause blindness) in people who have acquired immunodeficiency syndrome (AIDS). Valganciclovir is also used to prevent cytomegalovirus (CMV) disease in people who have received a heart, kidney, or kidney-pancreas transplant and who have a chance of getting CMV disease. Valganciclovir is in a class of medications called antivirals. It works by preventing the spread of CMV disease or slowing the growth of CMV.

How should this medicine be used?

Valganciclovir comes as a tablet and as an oral solution (liquid) to take by mouth. It is usually taken with food once or twice a day. To help you remember to take valganciclovir, take it around the same time(s) every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take valganciclovir exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Children may take the tablets or the oral solution; however, adults should *only* take the tablets.

The oral solution will be prepared by your pharmacist and they will also give you a device to measure your dose. Only use the measuring device provided to you to measure your solution.

Shake the oral solution well before each use.

Swallow the tablets whole; do not split, chew, break, or crush them.

Be careful when handling valganciclovir tablets or oral solution. Do not allow your skin, eyes, mouth, or nose to come into contact with broken or crushed valganciclovir tablets or oral solution. If such contact occurs, wash your skin well with soap and water or rinse your eyes well with plain water.

Valganciclovir helps to control CMV but does not cure it. Do not stop taking valganciclovir without talking to your doctor. Stopping to take valganciclovir too soon may cause the amount of CMV in your blood to increase or the virus to become resistant to this medication.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking valganciclovir,

- tell your doctor and pharmacist if you are allergic to valganciclovir, ganciclovir (Cytovene), any other medications, or any of the ingredients in valganciclovir tablets or oral solution. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: amphotericin B (Abelcet, Ambisome); imipenem-cilastatin (Primaxin); mycophenolate mofetil (CellCept); and probenecid. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had the conditions mentioned in the IMPORTANT WARNING section or any of the following conditions: kidney or liver disease, or if you are being treated with hemodialysis (a special machine that removes waste products from blood).
- tell your doctor if you are breastfeeding. You should not breastfeed while taking valganciclovir. Talk to your doctor about when you may safely begin breastfeeding after you stop taking valganciclovir.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking valganciclovir.
- you should know that valganciclovir may make you drowsy, dizzy, unsteady, confused, less alert, or cause seizures. Do not drive a car or operate machinery until you know how this medication affects you.

What special dietary instructions should I follow?

Drink plenty of fluids while you are taking valganciclovir.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. Then take the next dose at the usual scheduled time. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Valganciclovir may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea
- nausea
- vomiting
- pain, tenderness, or swelling of the abdomen
- eye pain
- constipation
- headache
- weight loss
- back, joint, or muscle pain
- mouth ulcers

- depression
- anxiety

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- seeing specks, flashes of light, or a dark curtain over everything
- decreased urination
- blood in urine
- vision problems
- swelling of the hands, arms, feet, ankles, or lower legs
- hives
- rash
- itching
- yellowing of skin or eyes; loss of appetite; dark urine; and/or light-colored bowel movements
- unintentional trembling or shaking movements
- numbness, pain, burning, or tingling in the hands or feet
- seizures

Valganciclovir may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store the tablets at room temperature and away from excess heat and moisture (not in the bathroom). Store the oral solution in the refrigerator for up to 49 days at 2–8°C; do not freeze.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist

or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- upset stomach
- vomiting
- stomach pain
- diarrhea
- shaking hands that you cannot control
- seizures
- decreased urination
- bloody urine
- sore throat, fever, chills, cough, or other signs of infection
- excessive tiredness
- pale skin
- yellowing of skin or eyes
- dizziness
- fast heartbeat
- weakness
- unusual bleeding or bruising

What other information should I know?

Do not let anyone else take your medication. Do not let your valganciclovir supply run out. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Valcyte[®]

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