valganciclovir (val-gan-sye-loyd-ev-er)

Valcyte

**Classification**
Therapeutic: antivirals

**Pregnancy Category**
C

**Indications**
Treatment of cytomegalovirus (CMV) retinitis in patients with AIDS. Prevention of CMV disease in kidney, kidney/pancreas and heart transplant patients at risk.

**Action**
Valganciclovir is a prodrug which is rapidly converted to ganciclovir by intestinal and hepatic enzymes. CMV virus converts ganciclovir to its active form (ganciclovir phosphate) inside host cell, where it inhibits viral DNA polymerase. Therapeutic Effects: Antiviral effect directed preferentially against CMV-infected cells.

**Pharmacokinetics**

**Absorption:** 59.4% absorbed following oral administration, rapidly converted to ganciclovir.

**Distribution:** Unknown.

**Metabolism and Excretion:** Rapidly converted to ganciclovir; ganciclovir is mostly excreted by the kidneys.

**Half-life:** 4.1 hr (intracellular half-life of ganciclovir phosphate is 18 hr).

**TIME/ACTION PROFILE (ganciclovir blood levels)**

<table>
<thead>
<tr>
<th>ROUTE</th>
<th>ONSET</th>
<th>PEAK</th>
<th>DURATION</th>
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<tbody>
<tr>
<td>PO</td>
<td>rapid</td>
<td>2 hr</td>
<td>12–24 hr</td>
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**Contraindications/Precautions**
Contraindicated in: Hypersensitivity to valganciclovir or ganciclovir; OB: Pregnancy or planned pregnancy; Lactation; Hemodialysis; Patients undergoing liver transplantation.

Use Cautiously in:
- Renal impairment (dosage adjustment recommended if CrCl ≤ 60 mL/min).
- Pre-existing bone marrow depression; Perioperative or concurrent myelosuppressive drug therapy or radiation therapy.
- Geri: Age-related renal function requires dosage reduction.
- Pedi: Children - time not established.

**Adverse Reactions/Side Effects**
CNS: SEIZURES, headache, insomnia, agitation, confusion, dizziness, hallucinations, paresthesia. OCULAR: blurred vision, dry eyes, floaters, vision changes, pain, worsening, MIR syndrome, retinopathy.

**Interactions**

**Drug-Drug:** 3 risk of hematologic toxicity with didanosine. Blood levels and effects may be increased by probenecid. Patients with renal impairment may experience accumulation of metabolites of mycophenolate and valganciclovir. Blood levels and risk of toxicity from didanosine.

**Route/Dosage**

**Treatment of CMV Disease**

PO (Adults): Induction—900 mg twice daily for 21 days; Maintenance treatment or patients with inactive CMV retinitis—900 mg once daily.

**Renal Impairment**

CCr 40–59 mL/min (Adults): Induction—450 mg twice daily for 21 days; Maintenance treatment or patients with inactive CMV retinitis—450 mg once daily.

**Prevention of CMV Disease in Transplant Patients**

PO (Adults): Kidney/pancreas, or heart transplant—900 mg once daily, starting 10 days prior to transplant and continued for 100 days after; Kidney transplant—900 mg once daily, starting 10 days prior to transplant and continued for 200 days after.

**Prevention of CMV Disease in Hematopoietic Stem Cell Transplant Patients**

PO (Adults): Allogeneic hematopoietic stem cell transplantation—450 mg once daily, starting 10 days prior to transplant and continued for 100 days after; Autologous hematopoietic stem cell transplantation—900 mg once daily, starting 10 days prior to transplant and continued for 200 days after.
Renal Impairment

**PO (Adults):** CCr 40–59 mL/min—450 mg once daily; CCr 25–39 mL/min—450 mg every 2 days; CCr 12–24 mL/min—450 mg twice weekly.

**PO (Children 4 mo-16 yr):** Kidney or heart transplant—Dose is based on body surface area (BSA) and CCr. Dose is based on CCr. All calculated doses should be rounded to nearest 25 mg (min—900 mg) and administered as oral solution, should be started 10 days prior to transplant and continued for 100 days after.

NURSING IMPLICATIONS

**Assessment**
- Diagnosis of CMV retinitis should be determined by ophthalmoscopy prior to treatment with valganciclovir.
- Culture for CMV (urine, blood, throat) may be taken prior to administration. However, a negative CMV culture does not rule out CMV retinitis. If symptoms do not respond after several weeks, resistance to valganciclovir may have occurred. Ophthalmologic exams should be performed weekly during induction and every 2 wk during maintenance or more frequently if the macula or optic nerve is threatened.
- Assess for signs of infection (fever, chills, cough, hoarseness, lower back or side pain, sore throat, difficult or painful urination). Notify health care professional if these symptoms occur.
- Assess for bleeding (bleeding gums, bruising, petechiae, or guaiac stools, urine, and emesis). Avoid IM injections and taking rectal temperatures. Apply pressure to venipuncture sites for 10 min.
- Lab Test Considerations: May cause granulocytopenia, anemia, and thrombocytopenia. Monitor neutrophil and platelet count closely throughout therapy. Do not administer if ANC ≤500/mm³; platelet count ≤50,000/mm³; or bilirubin >0.5 mg/dL. Recovery begins within 3–7 days of discontinuation of therapy.
- Monitor I&O and serum creatinine at least once every 2 wk throughout therapy. May cause ↑ in serum creatinine.

Potential Nursing Diagnoses

- Risk for infection (Indications) (Patient/Family Teaching)
- Implementation
  - Do not confuse valganciclovir with valacyclovir. Do not confuse Valcyte (valganciclovir) with Valtrex (valacyclovir).
  - PO: Administer tablets and oral solution with food. Adults should take tablets, not oral solution. Handle valganciclovir tablets carefully. Do not break or crush. May be potentially teratogenic; avoid direct contact with broken or crushed tablets. If contact with the skin or mucous membranes occurs, wash thoroughly with soap and water and rinse eyes thoroughly with plain water.

- Oral solution (5 mg/mL) must be prepared by the pharmacist prior to dispensing to the patient. Shake well prior to use. Use oral dispenser provided for accurate dose. Store oral solution refrigerated for no longer than 49 days.

- Patient/Family Teaching
  - Instruct patient to take valganciclovir with food, as directed. Take missed doses as soon as remembered, unless almost time for next dose; do not double doses. Advise patient in read Patient Information before starting therapy and with each Rx refill in case of changes.
  - Instruct patient that valganciclovir is not a cure for CMV retinitis. Progression of retinitis may continue in immunosuppressed patients during and following therapy. Advise patient to have regular ophthalmic exams at least every 3–6 mo. Duration of therapy for CMV prevention is based on the duration and degree of immunosuppression.
  - May cause seizures, sedation, dizziness, ataxia, and/or confusion. Caution patient not to drive or do other activities requiring alertness until response to medication is known.
  - Advise patient to notify health care professional if fever, chills, sore throat; other signs of infection; bleeding gums; bruising; petechiae; or blood in urine, stool, or emesis occurs. Caution patient to avoid crowds and persons with known infections. Instruct patient to use soft toothbrush and electric razor. Patient should be cautioned not to drink alcoholic beverages or take products containing aspirin or NSAIDs.
  - Advise patient that valganciclovir may have teratogenic effects. Women should use a nonhormonal during and for at least 30 days following therapy. If their female
Continued

Valganciclovir

Sexual partner can become pregnant, even if she does not menstruate. Advise men to use a barrier method of contraception during and for at least 90 days following therapy. Advise male patients that valganciclovir may lower the amount of sperm in a man’s body and cause fertility problems. Caution patients to use sunscreen and protective clothing to prevent photosensitivity reactions. Emphasize the importance of frequent follow-up exams to monitor blood counts.

Evaluation/Desired Outcomes

Management of the symptoms of CMV retinitis in patients with AIDS.
Prevention of CMV disease in kidney, kidney/pancreas, and heart transplant patients at risk.

Why was this drug prescribed for your patient?