

Alert	Oral valganciclovir is a cytotoxic agent.
Indication	1) Treatment of severe or moderately severe, symptomatic congenital CMV, or 2) Treatment of acute severe CMV disease.
Action	Valganciclovir is an L-valyl ester salt (prodrug) of ganciclovir which, after oral administration, is rapidly converted to ganciclovir by intestinal and hepatic esterases. Synthetic nucleoside analogue of 2-deoxyguanosine that inhibits replication of herpes viruses. Sensitive human viruses include cytomegalovirus, herpes simplex virus 1 and 2, herpes virus type 6, 7 and 8, Epstein-Barr virus, varicella zoster virus and hepatitis B virus.
Drug Type	Antiviral.
Trade Name	Valcyte
Presentation	Valganciclovir hydrochloride powder for oral solution. The reconstituted solution contains 50 mg/mL valganciclovir and appears clear, colourless to brownish-yellow in colour.
Dosage/Interval	16 mg/kg/dose 12 hourly* *In acute, severe CMV disease including hepatitis, use IV ganciclovir as initial therapy and change over to oral valganciclovir once clinically stable. Duration of treatment: 1. Treatment of severe or moderately severe, symptomatic congenital CMV – maximum 6 months. 2. Treatment of acute severe CMV disease – as per the disease progress and response.
Route	Oral
Preparation/Dilution	Valganciclovir is a cytotoxic agent. Refer to your local policy in regards to safety precautions/facilities required to reconstitute the powder for oral solution.
Administration	Valganciclovir is a cytotoxic agent. Follow full cytotoxic precautions as per local policy. Should be given with feeds and can be given with other medications.
Monitoring	Full blood count, particularly neutrophil count, should be followed weekly for 6 weeks, then at week 8, then monthly for the duration of therapy. Liver function tests monthly throughout therapy. Renal function tests.
Contraindications	Hypersensitivity to ganciclovir, valganciclovir, aciclovir or valacyclovir. Patients with: <ul style="list-style-type: none"> • absolute neutrophil count below $0.5 \times 10^9/L$, or • platelet count below $25 \times 10^9/L$ unless thrombocytopenia is related to CMV disease, or • haemoglobin less than 80 g/L (8 g/dL).
Precautions	Active component of valganciclovir (i.e. ganciclovir) has both gonadal toxicity and carcinogenicity in animal models and its long-term safety after administration to young children is not established.
Drug Interactions	Convulsions have been reported in patients receiving ganciclovir (metabolite of valganciclovir) and imipenem-cilastatin concurrently. Concurrent use of tacrolimus and ganciclovir increases nephrotoxicity.
Adverse Reactions	Commonly causes neutropenia. If absolute neutrophil count (ANC) falls below $0.5 \times 10^9/L$, and if it is thought not to be due to CMV disease, withhold medication until ANC is above $0.75 \times 10^9/L$, then restart medication at half dose. If ANC falls below $0.5 \times 10^9/L$ again, consider discontinuing the medication. Can also cause anaemia and thrombocytopenia. Discontinue medication if platelet count below $25 \times 10^9/L$ or haemoglobin less than 80 g/L occurs and is thought not to be due to CMV disease.
Stability	The reconstituted solution should be discarded 49 days after reconstitution.
Storage	Store powder for reconstitution below 25°C.

	After reconstitution, the solution should be stored in the refrigerator (2-8°C). Do not freeze.
Special Comments	
Evidence summary	Refer to full version.
References	Refer to full version.

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