Valganciclovir
Newborn Use Only

2017

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: • absolute neutrophil count below 0.5 x 10^9/L, or • platelet count below 25 x 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 x 10^9/L, and if it is thought not to be due to CMV disease, withhold medication until ANC is above 0.75 x 10^9/L, then restart medication at half dose. If ANC falls below 0.5 x 10^9/L again, consider discontinuing the medication. Can also cause anaemia and thrombocytopenia. Discontinue medication if platelet count below 25 x 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.

Original version Date: 18/09/2017	**Author: Jing Xiao**
Current Version number: 1.0	**Current Version Date:** 1.0
Risk Rating: Medium	**Due for Review:** 18/09/2020
Approval by: NMF Consensus Group	**Approval Date: 18/09/2017**

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