### 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 10⁹/L, or
- platelet count below 25 x 10⁹/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 10⁹/L, and if it is thought not to be due to CMV disease, withhold medication until ANC is above 0.75 x 10⁹/L, then restart medication at half dose. If ANC falls below 0.5 x 10⁹/L again, consider discontinuing the medication.

Can also cause anaemia and thrombocytopenia. Discontinue medication if platelet count below 25 x 10⁹/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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