| NEONATAL MEDICATION GUIDELINE | |
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| **Valganciclovir** | |
| **Scope (Staff):** | Nursing, Medical and Pharmacy Staff |
| **Scope (Area):** | KEMH NICU, PCH NICU, NETS WA |
| **This document should be read in conjunction with the Disclaimer.** | |

## Quick Links


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|---|---|---|---|
| Dose | Preparation & Administration | Side Effects & Interactions | Monitoring |


## Restrictions

**Formulary: Highly Restricted**

Requires Neonatologist or Microbiologist approval before commencing

**HIGH RISK Medication** ⚠

Valganciclovir is considered as a cytotoxic agent – adequate handling is recommended

Pregnant women or adults trying to conceive are recommended to avoid handling, preparing or administering this medicine.

## Description

Antiviral guanine analogue which inhibits viral DNA polymerase and DNA Synthesis – converted to the active drug, ganciclovir, in the body.

## Presentation

**Oral suspension (powder for reconstitution):** 50mg/mL

*Requires cytotoxic handling during preparation; prepared by PCH Pharmacy*

## Storage & Handling

**Powder for reconstitution:** Store at room temperature, below 25°C

**Reconstituted suspension:** Refrigerate at 2-8°C, do not freeze.

Cytotoxic handling required (refer to Preparation and Handling of Cytotoxic Waste for more information)

## Precautions and Contraindications

**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.
- Renal insufficiency.
- Due to the similarity of the chemical structure of ganciclovir and that of acyclovir, a cross-hypersensitivity reaction between these drugs is possible. Caution should be used when prescribing valganciclovir to patients with known hypersensitivity to aciclovir or to its prodrug valaciclovir.

**Contraindications:**

- Hypersensitivity to ganciclovir, valganciclovir, aciclovir or valaciclovir.
- Patients with any of the below:
  - absolute neutrophil count below 0.5 x $10^9$ /L
  - platelet count below 25 x $10^9$ /L unless thrombocytopenia is related to CMV disease
  - haemoglobin less than 80 g/L

## Dose

**<u>Treatment of congenital cytomegalovirus (CMV) infection</u>**

**Oral:**

16mg/kg every 12 hours*

*In acute, severe CMV disease, IV ganciclovir is used as initial therapy then changed to oral valganciclovir once clinically stable.

Oral doses will need to be assessed every 4 weeks and, based on weight gain, incrementally increased.

**<u>Duration of therapy</u>**

**Severe or moderately severe, symptomatic congenital CMV:**

Maximum 6 months.

**Acute, severe CMV:**

Per disease progress and response.

## Dose Adjustment

Dose reduction required in significant neutropenia – contact Microbiology for advice.

Renal impairment – adjust dose according to severity of renal insufficiency.

Hepatic impairment – insufficient data.

## Preparation

**Prepared by PCH Pharmacy** (contact KEMH Pharmacy to organise supply)

*Valganciclovir is a potential teratogen and carcinogen. Adequate procedures for the handling and disposal of cytotoxic agents should be followed. Pregnant women or adults trying to conceive are recommended to avoid handling, preparing or administering this medicine.*

Avoid inhalation and direct contact of the powder and solution with skin and mucous membranes. If such contact occurs, wash thoroughly with soap and water. If the powder or solutions gets into the eyes, rinse eyes thoroughly with water.

## Administration

**Oral**

1. Ensure PPE is worn when administering the dose:
   - Purple nitrile gloves
   - Goggles or Face Shield
   - Cytotoxic Mask
   - Cytotoxic grade gown
   - Covered shoes
2. Administer with feeds to enhance absorption.

## Side Effects

**Common:** neutropenia, anaemia, thrombocytopenia, fever, rash, abnormal liver function tests, chills, agitation, diarrhoea, tremor.

**Serious:** neutropenia*, thrombocytopenia*, haematuria, dysrhythmias.

*Seek specialist advice if haematological abnormalities develop.

## Interactions

May interact with IV medications – contact Pharmacy for advice

## Monitoring

**Therapeutic drug monitoring**

- Valganciclovir is a pro-drug of ganciclovir.
- Ganciclovir levels may be monitored on the advice of Infectious Diseases.
- Contact the duty Biochemist **prior** to collection of the sample.

**Serum CMV DNA**

- Monitor viral load as advised by Infectious Diseases.

**Other monitoring**

- FBP (particularly neutrophil and platelet count):
  - Baseline
  - Weekly for 2-3 weeks,
  - Then monthly during therapy
- LFTs:
  - Baseline
  - Then monthly during therapy
- Renal function
  - Baseline
  - Then monthly during therapy

## Handling of Cytotoxic Waste

**Disposing of body fluids – nappies:**

- All neonates should wear disposable nappies during valganciclovir treatment and for 48 hours after the last dose.
- When changing nappies don adequate PPE as described in Administration.
- Ensure that parents are aware that gloves must be worn at home and that they have a supply of them on discharge (see Homecare below for further details).
- Inpatient nappies and purple gloves must be placed in a plastic bag, sealed and then placed in the purple cytotoxic waste bin.

**Weighing of soiled nappies:**

- Where a neonate requires an accurate fluid balance assessment and nappies are required to be weighed, place the nappy in a plastic bag before placing it on the scales.

- Nappies are to be weighed immediately after removal then disposed of as above.

**Homecare:**

- Parents and carers of patients in nappies taking valganciclovir should be instructed to avoid contact with faecal matter and urine and use disposable nappies.
- Gloves should be worn whilst changing nappies and nappies double-bagged before disposal.
- Valganciclovir should not be disposed of via wastewater or household waste.
- Unused/expired medicines should be returned to pharmacy for disposal.
- For more information refer to Appendix 1: Homecare Guidelines – Administration of Oral Valganciclovir at Home in Queensland Health's guideline: Treatment Guideline for Infants with Congenital CMV Disease (health.qld.gov.au)

**Further Information:**

See WNHS Pharmaceutical and Medicines Management Guidelines: Cytotoxic and Hazardous Medications

## Comments

Pregnant women or adults trying to conceive are recommended to avoid handling, preparing or administering this medicine.

## Related Policies, Procedures & Guidelines

**CAHS Clinical Practice Guidelines:**

Cytomegalovirus (CMV) Neonatal Pathway

**WNHS Clinical Practice Guidelines:**

Antimicrobial Stewardship: Antimicrobial Restriction Category List

**WNHS Pharmaceutical and Medicines Management Guidelines:**

Cytotoxic and Hazardous Medications

## References

Children's Health Queensland Hospital and Health Service. Treatment Guideline for Infants with Congenital CMV Disease (cCMV). Queensland Government; 2021 [cited 2022 May 26]. Available from: Treatment Guideline for Infants with Congenital CMV Disease (health.qld.gov.au)

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Takemoto CK, Hodding JH, Kraus DM. Valganciclovir (Systemic). In: Pediatric & neonatal dosage handbook with international trade names index: a universal resource for clinicians treating pediatric and neonatal patients. 27th ed. Hudson (Ohio): Lexicomp; 2020. P2000-2003.

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The health impact upon Aboriginal people has been considered, and where relevant incorporated and appropriately addressed in the development of this document (insert ISD Number). (Please refer to the Aboriginal Health Impact Statement and Declaration for Department of Health and Health Service Provider Guidelines – please delete once you have completed this).

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