### Ganciclovir Sodium

**Other Names**
- Cytovene®, DHPG

**Classification**
- Antiviral

**Allergy Alert**
See Contraindications

### Indications for IV Use

**Health Canada Approved**
- For the treatment of cytomegalovirus (CMV) retinitis in immunocompromised patients.
- Prevention of CMV disease in transplant recipients.

**Non Health Canada Approved Indication but Substantiated in the Literature**
- Treatment of other life-threatening CMV infections.

**Spectrum of Activity**
- Cytomegalovirus, Herpes Simplex types 1, 2 & 6, Epstein-Barr virus, and Varicella Zoster Virus.

### Contraindications
- Hypersensitivity to ganciclovir or acyclovir.

### Cautions
- Patients with pre-existing cytopenias, with a history of cytopenic reactions to other drugs or with a history of exposure to known marrow toxic drugs, chemicals or irradiation.
- Patient should be adequately hydrated to promote renal excretion of drug.

### Drug Interactions
- Zidovudine: concomitant therapy may increase haematological toxicity. Avoid giving zidovudine during induction phase of ganciclovir. Monitor hematologic function and adjust dose as necessary.

### Pregnancy/Breast Feeding
Contact pharmacy for most recent information.

### Administration

<table>
<thead>
<tr>
<th>Mode</th>
<th>Direct into IV Tubing</th>
<th>Intermittent Infusion</th>
<th>Continuous Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO MAY GIVE</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
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<tr>
<td>Registered nurses with specialized skills - non-vesicant chemotherapy administration training.</td>
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#### Adult
- Pharmacy to prepare and dilute in 50 - 250 mL NS or D5W. Infuse over 60 minutes. Maximum concentration: 10 mg/mL.

#### Paediatric
- Pharmacy to prepare and dilute in 25 - 250 mL NS or D5W. Infuse over 60 minutes. Maximum concentration: 10 mg/mL.

#### Neonate
- Pharmacy to prepare and dilute to a concentration of 1 - 5 mg/mL. Infuse over 60 minutes.

### Requirements
- IV infusion instrument for concentrated solutions (5 - 10 mg/mL).

### Monitoring
- None

### Recommended
- Baseline CBC and platelet count, then
  - every two days during induction phase of therapy and weekly thereafter. If counts are low, counts should be performed more often.
  - daily in: haemodialysis patients
    - those in whom ganciclovir or other drugs have previously resulted in neutropenia
    - those with a baseline neutrophil count less than 1.0 G/L.
- Serum creatinine at least every 2 weeks.
- Check IV site for signs of infection or phlebitis.

### Reconstitution
- Reconstitute 500 mg vials with 10 mL preservative free sterile water. Resulting solution 50 mg/mL.
COMPATIBILITY/STABILITY
- Stable in NS or D5W at a concentration of 1 - 10 mg/mL for 35 days at room temperature or in the refrigerator.3,4 Store in refrigerator.
- For drug-drug compatibility, contact drug information.

ADVERSE EFFECTS
HEMATOLOGIC  Dose-limiting toxicity
- Neutropenia, usually occurs early in the treatment but may occur at any time. Recovery 3-7 days once drug is discontinued.5
- Thrombocytopenia, anaemia.

OCULAR
- Retinal detachment due to ganciclovir-induced resolution of retinitis

CENTRAL NERVOUS SYSTEM
- Confusion, headache, thought disorders, hallucinations, anxiety, abnormal reflexes, seizures, coma.

HEPATIC
- Abnormal liver function tests (ALT, AST, alkaline phosphatase).

GASTROINTESTINAL
- Diarrhoea, nausea, anorexia, vomiting, abdominal pain.

RENAL/GENITOURINARY
- Increase in serum creatinine or urea. Hematuria.

MISCELLANEOUS
- Phlebitis and/or pain at injection site.
- Fever, chills, sepsis, rash.

DOSE
NOTE: Stop therapy if absolute neutrophil count < 0.5 G/L or platelet count < 25 G/L. Therapy may be resumed if evidence of bone marrow recovery is observed.

ADULTS AND PEDIATRICS
CMV Infections:2
- Induction:  5 mg/kg every 12 hours for 14 - 21 days.
- Maintenance:  5 mg/kg daily for 7 days of each week or 6 mg/kg daily for 5 days of each week. Return to induction dose for patients who experience progression of disease. Give for duration of patient’s immunosuppression.

Prevention of CMV disease in transplant recipients:6
- 5 mg/kg every 12 hours for 7 - 14 days followed by a maintenance dose of 5 mg/kg once daily for 7 days of each week or 6 mg/kg once daily for 5 days of each week. Duration of therapy is dependent on duration and degree of immunosuppression.

NEONATE
- Limited information available at this time. The following regimen has been recommended.
- Induction:  5 - 7.5 mg/kg every 12 hours for 14 days.7
- Maintenance:  10 mg/kg three times weekly for 3 months.7

RENAL IMPAIRMENT ADJUSTMENTS:6
- Creatinine clearance mL/s  Induction dose and interval  Maintenance dose and interval
- greater than 1.2  5 mg/kg every 12 hours 5 mg/kg every 24 hours
- 0.8 - 1.2  2.5 mg/kg every 12 hours 2.5 mg/kg every 24 hours
- 0.4 - 0.8  2.5 mg/kg every 24 hours 1.25 mg/kg every 24 hours
- 0.2 - 0.4  1.25 mg/kg every 24 hours 0.625 mg/kg every 24 hours
- less than 0.2  1.25 mg/kg 3 times per week 0.625 mg/kg 3 times per week

HEPATIC IMPAIRMENT ADJUSTMENTS:6
- None required.

HEMO/PERITONEAL DIALYSIS:9
- Haemodialysis: as for creatinine clearance of less than 0.2 mL/s. Dose after dialysis.
- CAPD: as for creatinine clearance of less than 0.2 mL/s.
- CAVH: 2.5 mg/kg.d

MISCELLANEOUS
- Environmental concerns - Use chemotherapy precautions.
GANCICLOVIR - REFERENCES


