

Dose adjustments For *herpes zoster*, 1 g every 12 hours if estimated glomerular filtration rate 30–50 mL/minute/1.73 m² (1 g every 24 hours if estimated glomerular filtration rate 10–30 mL/minute/1.73 m²; 500 mg every 24 hours if estimated glomerular filtration rate less than 10 mL/minute/1.73 m²).

For treatment of *herpes simplex*, 500 mg (1 g in immunocompromised or HIV-positive children) every 24 hours if estimated glomerular filtration rate less than 30 mL/minute/1.73 m².

For treatment of *herpes labialis*, if estimated glomerular filtration rate 30–50 mL/minute/1.73 m², initially 1 g, then 1 g 12 hours after initial dose (if estimated glomerular filtration rate 10–30 mL/minute/1.73 m², initially 500 mg, then 500 mg 12 hours after initial dose; if estimated glomerular filtration rate less than 10 mL/minute/1.73 m², 500 mg as a single dose).

For suppression of *herpes simplex*, 250 mg (500 mg in immunocompromised or HIV-positive children) every 24 hours if estimated glomerular filtration rate less than 30 mL/minute/1.73 m².

Reduce dose according to estimated glomerular filtration rate for *cytomegalovirus prophylaxis* following solid organ transplantation (consult product literature).

● **PRESCRIBING AND DISPENSING INFORMATION** Valaciclovir is a pro-drug of aciclovir.

● **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: oral suspension

Tablet

CAUTIONARY AND ADVISORY LABELS 9

▶ **Valaciclovir (Non-proprietary)**

Valaciclovir (as Valaciclovir hydrochloride) 500 mg Valaciclovir 500mg tablets | 10 tablet [PoM] £20.59 DT = £2.47 | 42 tablet [PoM] £8.99-£86.30

▶ **Valtrex** (GlaxoSmithKline UK Ltd)

Valaciclovir (as Valaciclovir hydrochloride) 250 mg Valtrex 250mg tablets | 60 tablet [PoM] £123.28 DT = £123.28

Valaciclovir (as Valaciclovir hydrochloride) 500 mg Valtrex 500mg tablets | 10 tablet [PoM] £20.59 DT = £2.47 | 42 tablet [PoM] £86.30

5.3a Cytomegalovirus infections

ANTIVIRALS > NUCLEOSIDE ANALOGUES

Ganciclovir

31-May-2018

● INDICATIONS AND DOSE

Prevention of cytomegalovirus disease [pre-emptive therapy in patients with drug-induced immunosuppression]

▶ BY INTRAVENOUS INFUSION

▶ Child 12–17 years: Initially 5 mg/kg every 12 hours for 7–14 days, then maintenance 6 mg/kg once daily, on 5 days of the week, alternatively maintenance 5 mg/kg once daily

Prevention of cytomegalovirus disease [universal prophylaxis in patients with drug-induced immunosuppression]

▶ BY INTRAVENOUS INFUSION

▶ Neonate: (consult product literature).

▶ Child 1 month–16 years: (consult product literature)
▶ Child 17 years: 6 mg/kg once daily, on 5 days of the week, alternatively 5 mg/kg once daily

Treatment of cytomegalovirus disease [in immunocompromised patients]

▶ BY INTRAVENOUS INFUSION

▶ Child: Initially 5 mg/kg every 12 hours for 14–21 days, then maintenance 6 mg/kg once daily, on 5 days of the week, alternatively maintenance 5 mg/kg once daily, maintenance only for patients at risk of relapse; if disease progresses initial induction treatment may be repeated

Congenital cytomegalovirus infection of the CNS

▶ BY INTRAVENOUS INFUSION

▶ Neonate: 6 mg/kg every 12 hours for 6 weeks.

- **UNLICENSED USE** Not licensed for use in children under 12 years for the treatment of cytomegalovirus disease in immunocompromised patients.
- ▶ In neonates Not licensed for congenital cytomegalovirus infection of the CNS.
- **CONTRA-INDICATIONS** Abnormally low haemoglobin count (consult product literature) · abnormally low neutrophil count (consult product literature) · abnormally low platelet count (consult product literature)
- **CAUTIONS** History of cytopenia · potential carcinogen (including long-term carcinogenicity) · potential teratogen (including long-term teratogenicity) · radiotherapy
- **INTERACTIONS** → Appendix 1: ganciclovir
- **SIDE-EFFECTS**
 - ▶ **Common or very common** Anaemia · anxiety · appetite decreased · arthralgia · asthenia · bone marrow disorders · chest pain · chills · confusion · constipation · cough · depression · diarrhoea · dizziness · dysphagia · dyspnoea · ear pain · eye disorders · eye inflammation · eye pain · fever · flatulence · gastrointestinal discomfort · headache · hepatic function abnormal · increased risk of infection · insomnia · leucopenia · malaise · muscle complaints · nausea · neutropenia · night sweats · pain · peripheral neuropathy · renal impairment · seizure · sensation abnormal · sepsis · skin reactions · taste altered · thinking abnormal · thrombocytopenia · vomiting · weight decreased
 - ▶ **Uncommon** Alopecia · arrhythmia · deafness · haematuria · hypotension · infertility male · oral ulceration · pancreatitis · psychotic disorder · tremor · visual impairment
 - ▶ **Rare or very rare** Agranulocytosis · hallucination
- **ALLERGY AND CROSS-SENSITIVITY** Contra-indicated in patients hypersensitive to valganciclovir, aciclovir, or valaciclovir.
- **CONCEPTION AND CONTRACEPTION** Manufacturer advises women of childbearing potential should use effective contraception during and for at least 30 days after treatment; men with partners of childbearing potential should be advised to use barrier contraception during and for at least 90 days after treatment. Ganciclovir may cause temporary or permanent inhibition of spermatogenesis—impaired fertility observed in *animal* studies.
- **PREGNANCY** Manufacturer advises avoid unless potential benefit outweighs risk—teratogenicity in *animal* studies.
- **BREAST FEEDING** Manufacturer advises avoid—present in milk in *animal* studies.
- **RENAL IMPAIRMENT**

Dose adjustments Manufacturer advises reduce dose for patients receiving mg/kg dosing if creatinine clearance less than 70 mL/minute—consult product literature.
- **MONITORING REQUIREMENTS** Monitor full blood count closely (severe deterioration may require correction and possibly treatment interruption).
- **DIRECTIONS FOR ADMINISTRATION** Manufacturer advises, for *intravenous infusion*, give intermittently in Glucose 5% or Sodium Chloride 0.9%. Reconstitute with Water for