MONOGRAPH

Linezolid Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Oxazolidinone antibacterial.[1-4]

INDICATIONS AND RESTRICTIONS

- Linezolid is reserved for use in multidrug-resistant infections. Resistance to linezolid can develop with prolonged treatment or when sub-therapeutic doses are used.[3-5]
- Linezolid is active against Gram-positive organisms, including methicillin resistant *Staphylococcus aureus* (MRSA), coagulase negative staphylococci, vancomycin resistant enterococci (VRE) and penicillin-resistant strains of *Streptococcus pneumoniae*.[3, 5]
- It is not active against Gram-negative bacteria.[4, 6]

IV and oral: Protected (red) antibiotic

ChAMP approval is required prior to prescription.

CONTRAINDICATIONS

- Hypersensitivity to linezolid or any component of the formulation.[1, 6-8]
- Linezolid is contraindicated for use in patients with uncontrolled hypertension, phaeochromocytoma, thyrotoxicosis and patients who have been treated with a monoamine oxidase inhibitor (e.g. phenelzine or tranylcypromine) in the previous 2 weeks due to the risk of hypertension.[1, 3, 4, 6-9]

PRECAUTIONS

- Vigilant blood pressure monitoring is required in cases of uncontrolled hypertension and use of sympathomimetic agents, vasopressive agents and dopaminergic agents. In the event of an acute elevation in blood pressure, doses of vasoactive drugs may require adjustment. Contact Infectious Diseases for possible alternative antibiotic agents. [7, 9]
- Linezolid has been associated with myelosuppression, especially in patients with concurrent renal or hepatic impairment.[1, 3, 6]
- This drug has multiple serious drug interactions please consult PCH approved references or contact Pharmacy for further information on agents to avoid.[5, 9]
- Linezolid should be used with caution in patients with diabetes mellitus due to the risk of hypoglycaemia. Patients with diabetes mellitus may also be predisposed to developing neuropathy.[7]
- Patients should be counselled to avoid food rich in tyramine (e.g. mature cheeses, soy sauce and yeast extract) due to the increased risk of hypertension.[3, 9, 10]
- Patients should be instructed to report any tingling or altered sensation, blurred vision or vision changed throughout treatment.[7, 9]
- The IV infusion contains 50.24 mg of glucose per mL.[1]
- The oral granules for suspension contain 210.6 mg of sucrose per mL.[1]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 600 mg tablet
- 20 mg/mL oral granules for suspension (150 mL bottle)
- 2 mg/ mL Infusion

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

IV or Oral:

Usual dose:

- **Children ≥ 4 weeks to < 12 years:** 10 mg/kg/dose (to a maximum of 600 mg) 8 hourly. [3, 4, 9, 10]
    - Children prescribed oral linezolid 8 hourly, should space doses as far apart as possible across waking hours to assist with accurate therapeutic drug monitoring – see Monitoring section below.
- **Children ≥ 12 years:** 600 mg 12 hourly. [3, 4, 9, 10]
- Maximum recommended duration of therapy for oral and IV therapy is 28 days. [3, 4, 10]
- Longer courses have been used; however there is an increased risk of significant long term side effects including visual impairment, peripheral neuropathy and blood disorders

(including thrombocytopenia, anaemia, leucopenia and pancytopenia).[3, 4]

- Linezolid has excellent oral bioavailability (approximately 100%), consider switching to oral dosing as soon as clinically appropriate.[1, 2, 6, 9]

Oral:

Non-Tuberculosis mycobacterial infection:

- **Children ≥ 4 weeks to < 10 years:** 10 mg/kg/dose (to a maximum of 300mg) 12 hourly.[9]
- **Children ≥ 10 years:** 10 mg/kg/dose (to a maximum of 600 mg) 24 hourly. This dose may be reduced by up to 50% if serious adverse effects develop.[9]

Non-Tuberculosis mycobacterial infection (Cystic Fibrosis patients):

- **Children ≥ 4 weeks to < 12 years:** 10 mg/kg/dose (to a maximum of 600 mg) 8 hourly.[9]
- **Children ≥ 12 years:** 10 mg/kg/dose (to a maximum of 600 mg) 12 hourly.[9]

Dosing in Overweight and Obese Children: Dose based on total body weight and consider therapeutic drug monitoring to optimise therapy. [11-13]

Renal impairment:

- eGFR calculator
- No dosage adjustment required in renal impairment, although metabolites may accumulate when creatinine clearance is < 30 mL/minute, the clinical significance of this is unknown.[1, 4, 6, 7, 9]
- There is an increased incidence of some serious adverse events (e.g. thrombocytopenia and anaemia) in those with reduced renal function.[9]

Hepatic impairment:

- No dosage adjustment is required in mild to moderate hepatic impairment. There is minimal information on the use of linezolid in severe hepatic impairment, use with caution.[1, 4, 7, 9]

RECONSTITUTION & ADMINISTRATION

Reconstitution - Oral Suspension:

- Reconstitute with of water as follows: tap bottle until all granules flow freely; add approximately half the total volume of water as per the manufacturer's instructions for reconstitution and shake well to obtain a uniform suspension.[1, 8]
- Add remainder of the water and again shake well. [1, 8]
- Store reconstituted suspension in the original packaging to protect it from light and discard any remaining suspension after 21 days.[1]
- After the initial reconstitution, the suspension should not be shaken further. Prior to measuring the dose, the suspension should be inverted several times to resuspend.[1, 8, 9]

Administration - Oral suspension:

- Before use, mix gently by inverting the bottle several times, do NOT shake after the initial reconstitution. May be administered with or without food.[1, 8, 9]

Administration - tablets:

May be administered with or without food.[1, 8, 9]

Administration - IV infusion:

- Infuse undiluted over 30 to 120 minutes. Do not use if the solution contains particles, is hazy or discoloured.[2, 3, 7, 8]
- The IV infusion should be kept in the foil overwrap and protected from light until administration.[1, 2]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Sodium chloride 0.9%
- Glucose 5%
- Hartmann's[2]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

- Regular blood pressure monitoring and monitoring for peripheral neuropathy (tingling or altered sensation) should be conducted throughout treatment. [8-10]
- Lactic acidosis has been reported with linezolid use and acid-base status should be monitored, especially for prolonged courses.[1, 14]
- Renal, hepatic and haematological function (full blood count) should be monitored at baseline then weekly if prolonged therapy is required (i.e. longer than 7 days). More frequent monitoring may be required in patients at higher risk of bleeding, in those with pre-existing myelosuppression, or patient with impaired renal or hepatic function.[1, 3-5, 7, 8, 10, 14]
- Visual function tests for optic neuropathy should be conducted in patients on treatment for greater than 28 days or in those who report new visual symptoms (e.g. blurred vision or vision changes).[1, 7, 9, 14]
- Sodium levels should be considered in those patients on concurrent diuretics and/or those at risk of hyponatraemia or Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH).[7]

Therapeutic drug monitoring:

- Therapeutic drug monitoring (TDM) should be considered for any patient on > 14 days treatment, patients with renal or hepatic impairment, patients with Cystic Fibrosis and young children.[5, 15]
- TDM should be performed at least 48 hours after commencement of therapy or any dose changes. Samples should be taken in the 30 minutes prior to the next dose being administered.[16]

- Patients prescribed oral linezolid 8 hourly should space their doses as far apart as possible across waking hours to assist with TDM. When conducting TDM in this population group, the TDM sample should be taken prior to the 2nd dose of the day, at least 7 hours after the morning dose. This will allow the most accurate assessment of levels and toxicity.

Collection tube:

- Serum, no gel (RED) or Lithium heparin no gel (DKGNLITH)[15]
- Minimum volume required: 0.5 mL[15]
- The time, date and dose of the last administered dose should be noted on the collection form.[15]

Target trough levels:

- 2 – 6.5 mg/L taken in the 30 minutes prior to the next dose. [9, 15]
- Haematological toxicity has been associated with levels between 7 – 10 mg/L.[9]
- Peripheral neuropathy, optic neuropathy, lactic acidosis, myelosuppression may be associated with trough levels above 2 mg/L for an extended duration. Monitoring for associated symptoms mentioned above are required.[9]

ADVERSE EFFECTS

Common: diarrhoea or constipation, nausea, vomiting, abdominal pain, insomnia, taste disturbance, raised hepatic enzymes, candidiasis, anaemia, thrombocytopenia, myelosuppression (generally with extended treatment >10 days), headache.[3, 4]

Infrequent: hypertension, arrhythmia, eosinophilia, rash, itching, urticaria, injection site reactions, dizziness, insomnia, blurred vision, dry mouth, tongue discolouration, angioedema, hyponatraemia, peripheral neuropathy (mainly if treated for >28 days, may be reversible).[3, 4]

Rare: seizures, *Clostridioides difficile*-associated diarrhoea, allergy, lactic acidosis, severe cutaneous adverse reactions (SCARs), optic neuropathy, tooth discolouration (reversible after manual removal by a dentist).[3, 4]

STORAGE

- **IV:** Store below 25 °C and protect from light. Keep the IV bags in the foil outer-wrap until use.[1, 2]
- **Oral:** Store tablets and suspension (before and after reconstitution) below 25°C. Once suspension is reconstituted, store the suspension in the original packaging to protect it from light and discard any remaining suspension after 21 days.[1]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **linezolid**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines
Antimicrobial Stewardship Policy
ChAMP Empiric Guidelines and Monographs
KEMH Neonatal Medication Protocols

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