MONOGRAPH

Levosimendan

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	Critical Care 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

⚠ HIGH RISK MEDICINE ⚠

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring

DRUG CLASS

Levosimendan is a cardiac inotrope and vasodilator with calcium-sensitising properties.[1]

Levosimendan is a High Risk Medicine.

INDICATIONS AND RESTRICTIONS

- Levosimendan is restricted for prescribing by intensive care consultants, for use in a critical care area only, for the short term treatment of children with life-threatening complications of severe heart failure.
- Levosimendan is a special access scheme product. SAS application(s) must be completed in accordance with the TGA regulations.

CONTRAINDICATIONS

- Contraindications are relative as levosimendan can be lifesaving.
- Hypersensitivity to levosimendan or any component of the formulation.[2]
- Severe renal or hepatic impairment.[2]
- Severe hypotension and tachycardia.[2]
- Significant mechanical obstructions affecting ventricular filling or outflow or both.[2]

- History of Torsades de Pointes.[2]

PRECAUTIONS

- Hypotension, or at risk of hypotension – consider starting at a lower rate and titrate to response.[2]
- Correct hypovolaemia before administration.[2]
- Mild to moderate renal and hepatic impairment – may lead to reduced clearance of the active metabolite, which may result in more pronounced and prolonged effects. Use with caution.[2, 3]
- Correct hypokalaemia before administration – may further decrease serum potassium.[2]
- Tachycardia, atrial fibrillation, arrhythmias, coronary ischaemia, prolonged QT interval – use with caution.[2]

FORMULATIONS

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

- Levosimendan 12.5 mg/5 mL Vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

- **Children 0 to 18 years – IV Loading dose:** 6–24 microg/kg over 10 minutes, followed by a continuous infusion.[3-6]

  Consider starting with a lower loading dose in patients with concomitant IV vasodilators or inotropes.[2] Loading dose may be omitted if hypotensive.[7]

- **Children 0 to 18 years – Continuous IV Infusion:** 0.05–0.2 microg/kg/min, adjust according to response, usually for 24 hours.[1-6]

  Note: Rate changes take 30 to 60 minutes to take effect.[7]

Dosing in Overweight and Obese Children:

- Calculate dose by actual body weight up to 120 kg.[7]

Renal impairment:

- eGFR calculator
- Use with caution with mild to moderate impairment - may lead to increased concentrations of the active metabolite, which may result in more pronounced and prolonged effects. Contraindicated for severe impairment.[1, 2]

Hepatic impairment:

- Use with caution with mild to moderate impairment - may lead to increased concentrations of the active metabolite, which may result in more pronounced and prolonged effects.
- Contraindicated for severe impairment.[1, 2]

ADMINISTRATION

- Levosimendan must only be administered in a critical care area under continuous monitoring.
- Levosimendan solution may range from clear, yellow or orange during storage, with no loss of potency. Do not administer if particulate matter or other discolouration present.[2, 7]
- Dilute before administration.[7]

Patient's Weight	Concentration	Notes
10 kg or less	3 mg in 30 mL (100 microg/mL)	In a 3 kg patient 0.05 microg/kg/min = 0.1 mL/hour
Above 10 kg	12**.**5 mg in 50 mL (250 microg/mL)	In a 20 kg patient, 0.05 microg/kg/min = 0.24 mL/hour

- May be administered centrally (preferred) or peripherally.[7]
- Discard diluted solution after 24 hours.[7]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids: Glucose 5%.[7]

Compatible at Y-site: Digoxin, furosemide, glyceryl trinitrate.[7]

INCOMPATIBLE drugs: No data available. Do not mix or administer with any medications or fluids not listed above.[2]

MONITORING

- Continuous monitoring of electrocardiogram (ECG), blood pressure, heart rate.[2]
- Urine output.[2, 3]
- Serum electrolytes, especially potassium.[1]
- Consider monitoring haemodynamic effects for several days post infusion or until the patient is clinically stable as active metabolites have a prolonged duration of action.[1, 2]

ADVERSE EFFECTS

Common: Hypotension, headache, ventricular tachycardia, extrasystoles, atrial fibrillation, hypokalaemia, insomnia, dizziness, gastrointestinal disturbances, anaemia, nausea, vertigo, pain at injection site.[1, 3]

STORAGE

Store between 2–8^{o} C. Refrigerate. Do not freeze.[2]

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 **levosimendan**. Any variations to the doses recommended should be clarified with the prescriber prior to administration.

Related CAHS internal policies, procedures and guidelines

CAHS Policy Manual: High Risk Medicines

References

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