MONOGRAPH

Pentamidine isetionate 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

Antifungal/ antiprotozoal[1, 2]

INDICATIONS AND RESTRICTIONS

- Pentamidine isetionate is used in the treatment and prophylaxis of *Pneumocystis jirovecii* pneumonia in patients unable to use trimethoprim with sulfamethoxazole (cotrimoxazole).[1]
- Rarely, intravenous pentamidine isetionate may also be used in the treatment of protozoal infections due to *Leishmania* or *Trypanosoma* species.[1, 3]

IV: Monitored (orange) antifungal / antiprotozoal

- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet ChAMP Standard Indications
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

CONTRAINDICATIONS

- Hypersensitivity to pentamidine isetionate or any component of the formulation via any route (IV or inhaled).

PRECAUTIONS

- Pentamidine isetionate should be infused over 60-120 minutes as rapid infusion may result in severe hypotension, hypoglycaemia and/or cardiac arrhythmias. Ensure patient is supine throughout administration to reduce the incidence of sudden, severe hypotension.[4, 5]
- Severe adverse reactions may occurs during pentamidine isethionate infusion including; hypotension, hypoglycaemia, acute pancreatitis, cardiac arrhythmias or cardiac arrest.[4-7]
- Pentamidine isetionate has been shown to prolong the QT interval. Correct risk factors if possible and use with caution.[5]
- Care should be taken in patients with diabetes or glucose intolerance as hypoglycaemia or hyperglycaemia may occur during or after the infusion. Patients at risk should be monitored for four to six hours after completion of the infusion.[5]
- Avoid extravasation of pentamidine isetionate due to the risk of tissue necrosis.[1, 5-7]
- The use of foscarnet with pentamidine isetionate is contraindicated due to the serious risk of hypocalcaemia and nephrotoxicity. [1]
- Each 4 mg of pentamidine isetionate is equivalent to 2.3 mg of pentamidine base.[8]

FORMULATIONS

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

- 300 mg powder for injection vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates (< 4 weeks of age):

- Not routinely used in neonates, contact an Infectious Disease or Clinical Microbiology Consultant for advice.

IV: **Children ≥ 4 weeks** (doses are expressed as pentamidine isetionate)

- **Prophylaxis**: 4 mg/kg/dose (to a maximum of 300 mg) every 4 weeks.[9]
- **Treatment:** 4 mg/kg/day (to a maximum of 300 mg) once daily for 14-21 days.[1, 9]

Renal impairment:

eGFR calculator

Unless treatment is essential, avoid use of treatment dosing of pentamidine in renal impairment. If essential, the following dose adjustments are recommended.[10]

- eGFR > 30mL/minute – normal dosing
- eGFR 10-30mL/minute – normal dose every 36 hours
- eGFR < 10mL/minute – normal dose every 48 hours.

Note: There is no information regarding dose adjustments required for the prophylaxis dosing. Care should be taken with its use.

Hepatic impairment:

- No dosage adjustment is required in hepatic impairment, however it should be used with caution in patients with severe impairment.[5, 7]

RECONSTITUTION & ADMINISTRATION

- Reconstitute the 300 mg vial with 4.8 mL of **water for injection** to give a final concentration of 60 mg/mL.[4]
- Do not reconstitute with sodium chloride 0.9% due to the risk of precipitation.[5]

IV infusion:

- Dilute the required dose to a final concentration of 6 mg/mL or weaker with a compatible fluid and infuse over 60 to 120 minutes.[1, 4, 5]
- The infusion should be administered whilst the patient is supine due to the risk of hypotension.[8]
- Ensure the patient is well hydrated during administration.[1, 9]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Pentamidine isethionate should only be reconstituted with water for injection. There is a risk of precipitation if sodium chloride 0.9% is used to reconstitute the powder.[1, 4]

Compatible fluids:

- Glucose 5%

Compatible at Y-site:

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

MONITORING

- During pentamidine isetionate infusion, blood pressure should be monitored at baseline then every 15 minutes during and on completion of the infusion until blood pressure has normalised.[1, 3]
- Blood glucose levels should also be checked prior to infusion and on completion of infusion. Patients at risk hypoglycaemia should have their blood glucose levels monitored for four to six hours after completion of the infusion.[5]
- For patients on treatment doses, urea and electrolytes, serum creatinine, complete blood count and platelets should be monitored daily during the initial stages of treatment. This may be reduced to three times a week as treatment continues. Urinalysis, serum electrolytes, serum calcium, serum potassium and liver function tests should be conducted weekly.[1, 5, 7, 11]
- For patients prescribed treatment doses of pentamidine isetionate ECG should be monitored at baseline and regularly throughout treatment.[1, 11] For once monthly prophylaxis dosing of pentamidine isetionate ECG monitoring is not required.

ADVERSE EFFECTS

Reactions are more common with treatment course of pentamidine isetionate and usually occur within the first week of treatment. Adverse effects may continue for a number of weeks following cessation of pentamidine isetionate due to the persistence of pentamidine isetionate in tissues.[1]

Common: nausea, vomiting, diarrhoea, taste disturbance, rash, flushing, raised liver enzymes, dizziness, confusion, glucose abnormalities, hypotension (more common with a rapid infusion rate), hypocalcaemia, hypomagnesaemia, hyperkalaemia, bronchospasm, leucopenia, thrombocytopenia, anaemia, thrombophlebitis at injection site, nephrotoxicity (including azotaemia, haematuria) [1, 3]

Rare: cardiac arrhythmias, QT prolongation, pancreatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, perioral hypoaesthesia.[1, 3]

STORAGE

- Store vials below 25˚C[4, 8]

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 **pentamidine isetionate**. 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

References

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