MONOGRAPH

Pantoprazole (Intravenous)

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
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

Proton pump inhibitor [1]

INDICATIONS AND RESTRICTIONS

- Gastric acid suppression where oral therapy is not appropriate or tolerated.[2]
  - For example: upper gastrointestinal (GI) bleed, duodenal ulcer, gastric ulcer, reflux oesophagitis, gastrointestinal lesions refractory to H_2 antagonists, Zollinger-Ellison syndrome. [2, 3]
  - IV therapy should be discontinued as soon as oral therapy can be tolerated. [4]

CONTRAINDICATIONS

- Hypersensitivity to pantoprazole, other substituted benzimidazoles, any component of the formulation, or other proton pump inhibitors. [3]

PRECAUTIONS

- Enteric infections – Proton pump inhibitor therapy may be associated with an increased risk of *clostridium difficile* infection. [1, 3]
- Severe cutaneous adverse drug reactions - including erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalised exanthematous pustulosis (AGEP) have been reported. [3] Discontinue if symptoms develop and consider further evaluation. [3]
- Subacute cutaneous lupus erythematosus (SCLE) - has been associated with use of proton pump inhibitors in rare cases. [3] Consider SCLE and ceasing pantoprazole if lesions occur, especially in sun exposed areas and if accompanied with arthralgia. [3]
- Osteoporosis-related fractures of the hip, wrist or spine – there is an increased risk of development with proton pump inhibitor use. [3] This risk is increased with high doses, multiple daily doses and long-term therapy. [3] Patients at high risk should receive adequate vitamin D and calcium monitoring and supplementation if indicated. [3]
- Acute interstitial nephritis – may occur as an idiopathic hypersensitivity reaction. [3] Discontinue use if this occurs. [3]
- Long term therapy (>3 months) – has been associated with hypomagnesemia. [3] Hypomagnesemia may further precipitate hypocalcaemia and/or hypokalaemia. [3] Consider monitoring magnesium, calcium and potassium levels in patients on prolonged treatment, a pre-existing risk of hypocalcaemia/ hypokalaemia/ hypomagnesemia being treated with other drugs which may also cause hypomagnesemia (such as digoxin, diuretics.) [3]
- Absorption of Vitamin B_{12} (cyanocobalamin) – may be reduced with long term proton pump inhibitor therapy. [3] Consider supplementation if indicated. [1, 3]

FORMULATIONS

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

- Pantoprazole 40 mg powder for injection, vial.

Pantoprazole is **NOT** available as an oral formulation at PCH.

- Refer to AMH Children's Dosing Companion for a suitable oral alternative

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Dosing in Overweight and Obese Children: Calculate dose based on ideal body weight. [2]

Intravenous:

Acid Suppression (oral therapy not tolerated):

- ≥ 4 weeks of age: 1 – 2 mg/kg (maximum 40 mg/dose) every 12 – 24 hours [5, 6, 7, 8, 9]
    - Maximum: 80 mg/day [5, 6, 7, 8, 9]

Oral:

- Parenteral therapy should be discontinued once oral therapy is tolerated. [4]
- Pantoprazole is **NOT** available as an oral formulation at PCH.
    - Refer to AMH Children's Dosing Companion for a suitable oral alternative.

Renal Impairment:

- No adjustment required. [2]

Hepatic impairment:

- Accumulation may occur in hepatic impairment with high dose use. [1] Monitor for adverse effects. [1]

RECONSTITUTION & ADMINISTRATION

Reconstitution:

- Reconstitute with 10 mL sodium chloride 0.9% to make a concentration of 4 mg/mL. [10, 11]

Administration:

- **IV Injection:** Inject undiluted over at least 2 minutes. [10, 11]
- **IV Infusion:** Dilute to a final concentration between 0.4 - 0.8 mg/mL and infuse over at least 15 minutes. [10, 11]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

Sodium chloride 0.9%	All concentrations [11]
Glucose 5%, Hartmann's	Pantoprazole 0.8 mg/mL or weaker. [10, 11]
Glucose 10%	Pantoprazole 0.4 mg/mL or weaker. [11]
Potassium chloride 20 mmol/L	Pantoprazole (Sun or Sandoz brands) 0.8mg/mL at Y-site [10, 11]

Compatible at Y-site: Pantoprazole compatibility is concentration dependent, do not mix undiluted pantoprazole with any other drugs. There is limited Y-site compatibility information, ask the clinical pharmacist for advice. [10]

INCOMPATIBLE drugs:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently. Consult a clinical pharmacist.

MONITORING

- Liver function tests (LFTs) at baseline and throughout treatment in long term use. [2, 7]
- Serum magnesium, calcium, and zinc at baseline and periodically if long term use. [2, 7] Consider vitamin B12 screening in prolonged therapy. [12]
- Symptoms of enteric infections such as clostridium difficile-associated diarrhoea.[2]
- Bone loss/bone mineral density in those receiving prolonged or high dose therapy. [2]

ADVERSE EFFECTS

Common: headache, nausea, vomiting, diarrhoea, abdominal pain, constipation, flatulence, injection site thrombophlebitis. [1, 3]

Infrequent: rash, itch, dizziness, fatigue, drowsiness, insomnia, dry mouth, increased sweating. [1]

Rare: gynaecomastia, myalgia/arthralgia, acute interstitial nephritis, electrolyte disturbances, peripheral oedema, hepatitis, jaundice, thrombocytopenia, leukopenia, hypersensitivity reactions (e.g. anaphylaxis, Stevens-Johnson syndrome), subacute cutaneous lupus erythematous (very rare). [1]

STORAGE

Vial: Store below 25°C. Protect from light. [3, 10]

Reconstituted solution

Somac brand	Stable at 2-8°C for 12 hours. [10]
EDTA Free (Sandoz and Sun brands)	Stable at 2-8°C for 12 hours or stable at 25°C for 24 hours. [10]

Infusion solution

Somac brand	Concentrations of 0.16-0.8 mg/mL in sodium chloride 0.9% or glucose 5% are stable for 24 hours below 25°C or at 2-8°C. [10]
EDTA Free (Sandoz and Sun brands)	Concentrations of 0.4 mg/L or 0.8 mg/mL in sodium chloride 0.9% or glucose 5% are stable for 24 hours below 25°C or at 2-8°C. [10]

INTERACTIONS

- Pantoprazole is metabolised by CYP450 enzymes including CYP2C19, CYP2D6 and CYP3A4. [2, 4] Concomitant administration of pantoprazole with other drugs that are metabolised by these enzymes including tacrolimus and fluvoxamine should be avoided where possible. [2 ,4]
- The absorption of drugs in which the bioavailability is pH dependent (e.g., ketoconazole, itraconazole, posaconazole) may be reduced. [2]
- Pantoprazole should be used with caution in patients treated with mycophenolate mofetil. [2]
- Pantoprazole should be avoided with use of high dose methotrexate due to an increased risk of methotrexate toxicities. [2]
- HIV protease inhibitor treatment (atazanavir or nelfinavir) – absorption may be impacted by proton pump inhibitor therapy.[3] Consider alternative gastric acid suppression therapy.[3]
- 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* **pantoprazole**. *Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

Drug Dosing in Overweight and Obese Children

Neonatal Medication Protocols

References

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