



MONOGRAPH

ESOMEPRAZOLE

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
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DRUG CLASS¹

Proton Pump Inhibitor (PPI)

Binds to the hydrogen/potassium ATPase enzyme system (proton pump), inhibiting both stimulated and basal acid secretion.

INDICATIONS AND RESTRICTIONS²

Approved for the prescription in patients who meet ONE the following criteria:

- Suspected or confirmed GORD (maximum of one month therapy)
- Gastro-oesophageal bleeding
- Gastro-oesophagitis that is confirmed via endoscope.
- As part of triple for H. Pylori eradication
- Post oesophageal reconstruction surgery.; maximum of two weeks therapy.
- Patients at high risk of GI Bleeding (high dose steroids/NSAID's, severe sepsis/shock, oesophageal varices, prolonged fasting in critical illness)

Esomeprazole **10 mg granules** are only approved for the above indications in patients with feeding tubes (PEJ, PEG, NJ, NG), who cannot take the medication orally and are at risk of a clogged tube. Patients without feeding tubes should be prescribed omeprazole, esomeprazole, or lansoprazole dispersible tablets.

CONTRAINDICATIONS¹

- Hypersensitivity to esomeprazole: (or omeprazole) or any component of the formulation.

PRECAUTIONS³

- Malignancy: Symptomatic response does not preclude malignancy.
- Acute interstitial nephritis: May occur at any time during therapy and is generally due to an idiopathic hypersensitivity reaction.
- Vitamin B12 deficiency: Malabsorption of Vitamin B12 (cyanocobalamin) may occur with long term (≥ 2 years) therapy.
- Hypomagnesemia.
- Fractures: Increased incidence of osteoporosis related fractures with long term (≥ 1 year) therapy.
- Drug-induced subacute cutaneous lupus erythematosus (SCLE): Can occur weeks, months or even years after exposure to esomeprazole.
- Gastro-intestinal infections: Increased risk of infections such as Salmonella, Campylobacter and Clostridium difficile.

FORMULATIONS²

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

- Esomeprazole 10 mg enteric coated granules, sachet for oral suspension
- Esomeprazole enteric coated tablets, 10 mg and 20 mg

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS⁴

Esomeprazole is not indicated in neonates. Use PCH Omeprazole Suspension 2 mg/mL.

Renal impairment:

- Use with caution in severe renal impairment⁴ [eGFR calculator](#)

Hepatic impairment:

Dose adjustment is required in patients with severe hepatic impairment⁴

- 1 to 11 years: maximum 10mg daily
- 12 to 17 years: maximum 20mg daily

Symptomatic GORD without erosive oesophagitis⁵**1–12 years (≥ 10 kg)**

Oral 10 mg once daily

12–18 years

Oral 20 mg once daily

GORD with erosive oesophagitis⁴**1–12 months**

3–5 kg: Oral 2.5 mg once daily

5–7.5 kg: Oral 5 mg once daily

>7.5 kg: Oral 10 mg once daily

1–12 years

< 20kg: Oral 10mg once daily

≥ 20kg: Oral 20mg once daily

12–18 years

Oral 20 to 40 mg once daily

Helicobacter pylori eradication⁵**4–18 years**

Give with 2 antibacterials. Refer to [ChAMP Enteric Infections Guideline](#).

<30 kg, oral 10 mg twice daily.

>30 kg, oral 20 mg twice daily.

RECONSTITUTION & ADMINISTRATION^{3,6}**Esomeprazole enteric coated tablets****Oral administration**

Esomeprazole enteric coated tablets should be swallowed whole with liquid. The enteric coated tablets can be dispersed in an appropriate volume of noncarbonated water. No other liquids should be used. Stir until the enteric coated tablet disintegrates and drink the liquid with the pellets immediately or within 30 minutes. Rinse the glass with water and drink. Do NOT crush or chew the pellets.³

Enteral administration**Size 8 French and larger**

- Disperse the tablet in 50 mL of water in an oral dispenser and shake for 2 minutes.
- Administer 5–10 mL into the tube, then stop and invert and shake the oral dispenser, making sure that the tip is not blocked.
- Repeat until all the dose is given then flush the tube with 50mL of water.
- Give the dose within 30 minutes of dispersing the tablet.

Size 16 French and larger

- Follow the same procedure as for size 8 French and larger however it is possible to disperse the tablet in 10 mL of water and flush the tube with 20 mL of water without causing blockage.

Esomeprazole Granules for oral suspension

Esomeprazole granules for suspension can be administered via a large syringe (30mL) through a nasogastric or gastric tube size 6 French or larger.

- Add the contents of each 10mg sachet to a syringe containing 15mL of water.
- Shake the enteral syringe and leave for a few minutes to thicken.
- Shake again and administer the prescribed dose through the nasogastric/gastric tube.
- To ensure no medication residue is left in the syringe, refill the syringe with 15mL of water, shake and administer through the nasogastric/gastric tube. Flush the enteral feeding tube with an additional volume of water after administration to prevent blockages.
- Give the dose within 30 minutes of dispersing the granules.
- Cool water only should be used (not warm/hot water or carbonated water).

If the recommended volumes are too large, consider switching to lansoprazole oral disintegrating tablets.

MONITORING

- Regular review is required in patients on long term treatment (≥ 1 year);³ PPIs may mask symptoms and delay diagnosis of gastric carcinomas.¹
- Measurement of serum magnesium concentrations should be considered before and during prolonged treatment, especially if prescribed with other drugs known to cause hypomagnesaemia.³
- Patients at risk of osteoporosis should maintain an adequate intake of calcium and vitamin D (colecalfiferol).³

ADVERSE EFFECTS¹

Common: headache, nausea, vomiting, diarrhoea, abdominal pain, constipation, flatulence

Infrequent: rash, itch, dizziness, fatigue, drowsiness, insomnia, dry mouth

Rare: myalgia/arthralgia, acute interstitial nephritis, peripheral oedema, hepatitis, jaundice, thrombocytopenia, leucopenia, hypersensitivity reactions (e.g., anaphylaxis, Stevens-Johnson syndrome), subacute cutaneous lupus erythematosus (very rare)

STORAGE³

Store below 25°C.

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

Related CAHS internal policies, procedures and guidelines

[Gastrostomy and Gastro-jejunal Tube Management \(health.wa.gov.au\)](https://health.wa.gov.au)


Calcium Monograph [CALCIUM \(health.wa.gov.au\)](https://health.wa.gov.au)

Colecalciferol Monograph [\(health.wa.gov.au\)](https://health.wa.gov.au)

References

1. Australian Medicines Handbook. Pharmaceutical Society of Australia 2024 [Internet] [cited July 2024] [Esomeprazole - Australian Medicines Handbook \(health.wa.gov.au\)](https://health.wa.gov.au)
2. Formulary ONE Online 2024 [Internet] [cited July 2024] [Paediatric - WA Statewide Medicines Formulary \(health.wa.gov.au\)](https://health.wa.gov.au)
3. MIMS Online [Internet] [cited July 2024] [MIMS | MIMS | Full Product Information \(health.wa.gov.au\)](https://health.wa.gov.au)
4. British National Formulary for Children [Internet] [cited 2024] [MedicinesComplete — CONTENT > BNF for Children > Drug: Esomeprazole \(health.wa.gov.au\)](https://health.wa.gov.au)
5. Australian Medicines Handbook – Children's Dosing Companion. Pharmaceutical Society of Australia. [Internet] [cited July 2024] [Esomeprazole - AMH Children's Dosing Companion \(health.wa.gov.au\)](https://health.wa.gov.au)
6. MIMS Don't Rush to Crush [Internet] [cited July 2024] [MIMS | Crush? \(health.wa.gov.au\)](https://health.wa.gov.au)

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