

Norfolk and Waveney ICB

Guideline

Document Control Sheet

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Name of document	Proton Pump Inhibitors (PPIs) for paediatric and neonatal patients >1 month old
Version	1.0
Date of this version	December 2024
Produced by	N.Cunningham
What is it for?	To provide guidance on safe, cost effective PPI prescribing in neonatal and paediatric patients. To standardise the prescribing of PPIs in neonatal and paediatric patients across the East of England.
Evidence base	Based on East of England Regional Guideline
Who is it aimed at and which settings?	Primary and secondary care
Consultation	
Impact Assessment:	
Other relevant approved documents	
References:	
Monitoring and Evaluation	
Training and competences	
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Version Control

Date	Summary of changes	Author(s)	Version Number
December 2024	New Guideline	N.Cunningham	1.0

1. Introduction

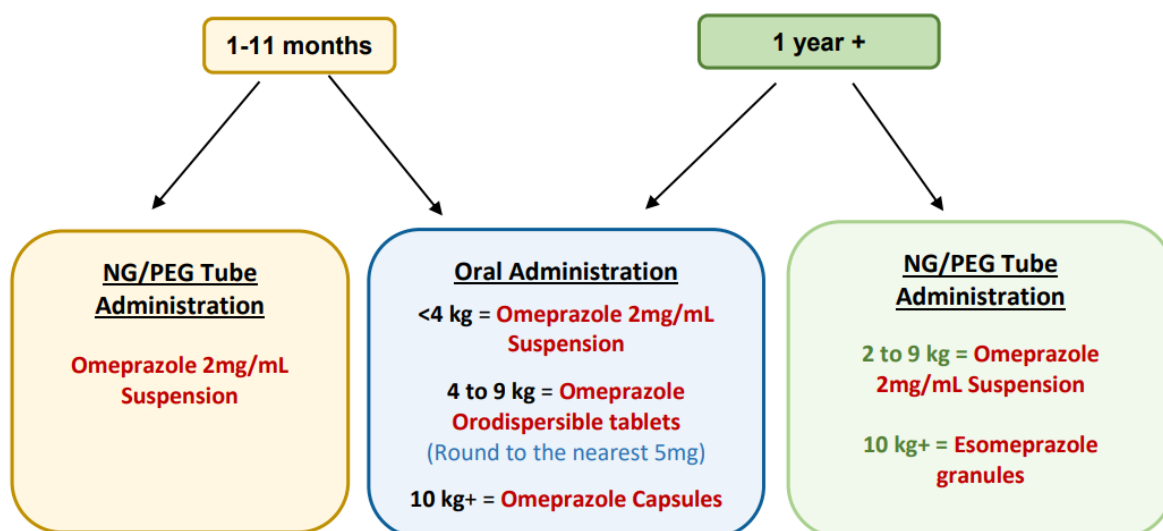
Proton pump inhibitors (PPIs) effectively reduce gastric acid secretion and are one of the main treatments for gastro-oesophageal reflux disease (GORD). PPIs are indicated for use in patients for:

- GORD that has not responded to other treatments such as feed thickeners or simple antacids
- Persistent or significant symptoms of reflux oesophagitis despite other measures
- Prevention or treatment of peptic ulceration (e.g. alongside long term steroids or non-steroidal anti-inflammatory drugs)
- H. pylori eradication regimens

In infants, GORD may be difficult to distinguish from uncomplicated gastro-oesophageal reflux. Uncomplicated gastro-oesophageal reflux is a physiological process that involves spitting up. It affects up to 60% to 70% of infants at age 3 to 4 months and resolves spontaneously with standing and walking by 12 months. Uncomplicated gastro-oesophageal reflux does not require PPI treatment.

Treatment with a PPI should be reviewed regularly to consider continued need, dose optimisation/reduction and suitability of formulation.

2. Treatment summary



NG - nasogastric, PEG - percutaneous endoscopic gastrostomy

3. Omeprazole dosing

Children with intestinal failure are unlikely to absorb PPIs as well, therefore doses at the higher end of the range are more likely to be used in this cohort.

Weight (kg)	Once daily dose	Maximum Daily dose
<10	0.7mg/kg	3 mg/kg/day (Max 20 mg).
10 – 19	10mg	20mg
20 +	20mg	40mg

4. Esomeprazole dosing

Age (years)	Weight (kg)	Once Daily Dose	Comments
1 – 11	10 -19	10 mg	Consider higher doses in erosive reflux oesophagitis
1 – 11	20kg and over	10 – 20mg	Consider higher doses in erosive reflux oesophagitis In patients with severe liver impairment – maximum daily dose = 10mg
12 – 17		20 – 40mg	In patients with severe liver impairment – maximum daily dose = 20mg

5. Additional administration details

I. Omeprazole suspension

- The container is two compartment system containing powder both in the cap and in the bottle.
- The two powders need to be combined and are then to be reconstituted with water.
- 2mg/mL and 4mg/mL are mint flavoured sugar-free suspension.
- Store in fridge (2-8°C) once reconstituted. 28 day expiry.
- Compatible with all tube types. Flush with 2-5mL of water after use.

II. Omeprazole Losec MUPs

- Dose should be rounded to the nearest half or whole tablet (5mg or 10mg). The tablets can be halved.
- The tablet must not be crushed or chewed.
- Tablets can be dispersed in water, fruit juice or fruit puree prior to administration. The dispersion should be taken immediately (or within 30 minutes) and always be stirred just before drinking and rinsed down with half a glass of water.
- Part doses MUST NOT be withdrawn from dissolved tablets.
- Compatible with NG / PEG tubes of French size 6 or larger. Flush with 10-20mL of water after use.

III. Omeprazole capsules

- Omeprazole capsules can be opened and dispersed in water or soft foods e.g. yoghurt, jam or apple puree. Do not mix with milk or carbonated liquids.
- The enteric coated pellets must not be chewed.

IV. Esomeprazole granules

- Add the contents of each 10 mg sachet into 15 ml of water. For 20mg add to 30mL of water.
- Stir and leave for a few minutes to thicken. Stir again and draw the suspension into a syringe and administer through enteric tube within 30 minutes after reconstitution.
- Compatible with NG / PEG tubes of French size 6 or larger. Flush with 10-20mL of water after use.

6. Administration via jejunal tubes

For administration of a PPI via jejunal tube (either direct, or as an extension to a gastric tube) omeprazole suspension should always be used, to reduce the risk of blockage and the need for surgical replacement. Please note that use of omeprazole suspension in these tube types is unlicensed, but anecdotally it does not block tubes.

Omeprazole suspension dosing guidance:

Weight	Omeprazole formulation	Dosing
< 10 kg	Omeprazole oral suspension 2mg/mL (10mg/5mL)	0.7mg/kg (max 3mg/kg) daily
10 kg to 19 kg	Omeprazole oral suspension 4mg/mL (20mg/5mL)	10mg (max 20mg) daily
≥ 20 kg	Omeprazole oral suspension 4mg/mL (20mg/5mL)	20mg (max 40mg) daily

Tube should always be adequately flushed before and after PPI administration with at least 5mL of water (2mL can be used in neonates).

6. Adverse effects

I. Side effects of PPIs as listed in the [BNF for Children](#)

Common or very common:

Abdominal pain; constipation; diarrhoea; dizziness; dry mouth; gastrointestinal disorders; headache; insomnia; nausea; skin reactions; vomiting.

Uncommon:

Arthralgia; bone fractures; confusion; depression; drowsiness; leucopenia; malaise; myalgia; paraesthesia; peripheral oedema; thrombocytopenia; vertigo; vision disorders.

II. Long-term use of PPIs (>12 weeks)

Long term use of PPIs in children is associated with a low risk of additional adverse events.

The potential long-term risks of PPI use in children include:

- Increased risk of infections: PPIs can reduce the acidity in the stomach, which may increase the risk of certain infections, such as pneumonia, gastroenteritis, and *C. difficile* infection.
- Increased risk of fractures: Studies have suggested that long-term PPI use may be associated with an increased risk of bone fractures, particularly in older adults. While the evidence is less clear in children, some studies have suggested that long-term PPI use may be associated with a slightly increased risk of bone fractures in this population as well.
- Vitamin and mineral deficiencies: PPIs can reduce the absorption of certain vitamins and minerals, such as calcium, magnesium, and vitamin B12. This can lead to deficiencies over time, which may have long-term health consequences.
- Changes in gut microbiome: PPIs may alter the balance of bacteria in the gut, which may have long term effects on digestive health and immune function.

It is important to note that the risks of long-term PPI use in children should be balanced against the potential benefits from treatment. In many cases, the benefits of PPIs may outweigh the risks, particularly if the medication is used appropriately and under the supervision of a healthcare provider. However, if long-term PPI use is necessary, regular monitoring for potential side effects and adjustments to the treatment plan may be needed to minimise risks. Treatment with a PPI should be reviewed regularly to consider continued need, dose optimisation/reduction and suitability of formulation.

7. Interactions

Please refer to the [BNF for Children](#)

- Omeprazole and esomeprazole may interfere with the absorption of drugs where gastric pH is critical to bioavailability such as posaconazole, itraconazole, ketoconazole, HIV inhibitors.
- Omeprazole is predicted to decrease the efficacy of clopidogrel. Manufacturers advise to avoid this combination.
- Omeprazole and esomeprazole are predicted to increase exposure to citalopram and escitalopram. Manufacturer advises monitor and adjust dose.
- When given together with PPIs, methotrexate levels have been reported to increase in some patients. In high-dose methotrexate treatment a temporary withdrawal of PPIs may need to be considered.

8. References

Adapted from the 2024 East of England Regional Guideline – East of England Paediatric Gastroenterology Network (EEPGN), Proton Pump Inhibitors (PPIS) for paediatric and neonatal patients over 1 month, by Emma Wilkinson and Aberdeen Young.

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