Improving lives together
Norfolk and Waveney Integrated Care System

NHS
Norfolk and Waveney
Integrated Care Board

Norfolk and Waveney Guideline

Proton Pump Inhibitors (PPIs) for Paediatric and Neonatal Patients aged >1 month

---

Document Control Sheet

This document can only be considered valid when viewed via the ICB's intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one online.

Approved documents are valid for use after their approval date and remain in force beyond any expiry of their review date until a new version is available.

Name of document	Proton Pump Inhibitors (PPIs) for Paediatric and Neonatal Patients >1 month old
Version	2.0
Date of this version	April 2025
Produced by	Medicines Optimisation Team (NC)
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	
Reviewed by:	
Approved by:	Norfolk & Waveney ICB Medicines Optimisation Programme Board
Date approved:	January 2025
Signed:	
Dissemination:	Knowledge NoW
Date disseminated:	January 2025
Review Date:	January 2027
Contact for Review:	Norfolk & Waveney ICB Medicines Optimisation Team

Version Control

Date	Summary of changes	Author(s)	Version Number
December 2024	New Guideline	Medicines Optimisation Team (NC)	1.0
April 2025	ICB & ICS logo's added to cover page. Formatting of *'2. Treatment summary for oral administration, NG or PEG'* changed; made larger and links to SPC for the omeprazole oral suspension sugar free added. Amendments to formatting of the following tables: in section 3 *'Omeprazole dosing guidance'*, in section 4 *'Esomeprazole dosing guidance'*, and in section 6 *'Omeprazole suspension dosing guidance for administration via jejunal tubes'*.		2

.

1. Introduction

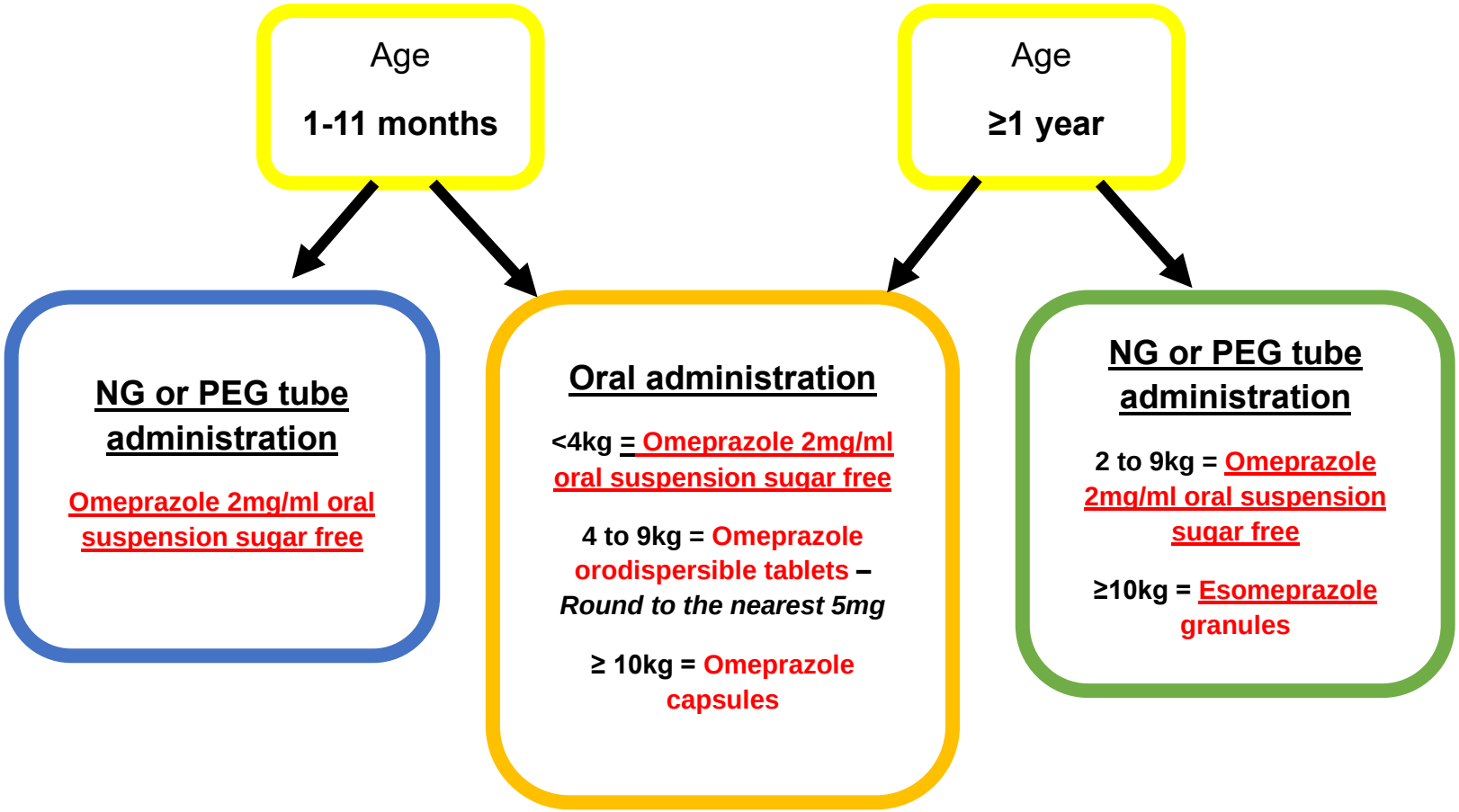
Proton pump inhibitors (PPIs) effectively reduce gastric acid secretion and are one of the main treatments for gastro-oesophageal reflux disease (GORD). PPIs are indicated for use in patients for:

- 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 for oral administration, NG or PEG



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.

Omeprazole dosing guidance		
Weight	**Daily dose**	**Maximum daily dose**
< 10 kg	0.7mg/kg once daily	3mg/kg once daily
10 kg to 19 kg	10mg once daily	20mg once daily
≥ 20 kg	20mg once daily	40mg once daily

4. Esomeprazole dosing

Esomeprazole dosing guidance			
Age	**Weight**	**Daily dose**	**Comments**
1 – 11 years	10 – 19 kg	10mg once daily	Consider higher doses in erosive reflux oesophagitis
	≥ 20 kg	10 – 20mg once daily	Consider higher doses in erosive reflux oesophagitis. In patients with severe liver impairment the maximum daily dose is 10mg.
12 – 17 years		20 – 40mg once daily	In patients with severe liver impairment the maximum daily dose is 20mg.

5. Additional administration details

I. Omeprazole oral 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 suspensions.
- 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:

Omeprazole suspension dosing guidance for administration via jejunal tubes			
Weight	**Omeprazole formulation**	**Daily dose**	**Maximum daily dose**
< 10 kg	Omeprazole oral suspension sugar free 2mg/mL (10mg/5mL)	0.7mg/kg once daily	3mg/kg once daily
10 kg to 19 kg	Omeprazole oral suspension sugar free 4mg/mL (20mg/5mL)	10mg once daily	20mg once daily
≥ 20 kg	Omeprazole oral suspension sugar free 4mg/mL (20mg/5mL)	20mg once daily	40mg once 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.

Rosen R, Vandenplas Y, Singendonk M, et al. Pediatric gastroesophageal reflux clinical practice guidelines: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. *J Pediatr Gastroenterol Nutr.* 2018;66(3):516-554.

Rosen R. Gastroesophageal reflux in infants: more than just a pHenomenon. *JAMA Pediatr*. 2014;168(1):83-89.

Gastro-oesophageal reflux disease in children and young people: diagnosis and management NICE guideline [NG1]. Published: 14 January 2015 Last updated: 09 October 2019. [Accessed April 2024].

British National Formulary for Children: Omeprazole, Esomeprazole Monographs [Internet]. Via Medicines Complete. 2024 [Accessed April 2024].

Rosemont pharma. Omeprazole Monograph. https://www.rosemontpharma.com/products/omeprazole-powder-oral-suspension. [Accessed April 2024]

Handbook of Drug Administration via Enteral Feeding Tubes. Via Medicines Complete 2015 [Accessed April 2024]

Wrexham Maelor Hospital Pharmacy Department. The NEWT Guidelines 2019. Omeprazole, Esomeprazole monograph. Available from: www.newtguidelines.com. [Accessed April 2024].