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# HSC Guideline on the use of Proton Pump Inhibitors in Paediatrics

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The aim of this guideline is to standardise prescribing practice of proton pump inhibitors (PPIs) in children in Northern Ireland whilst ensuring patients are given appropriate and effective treatments.

This guideline covers the use of PPIs in neonates and paediatrics, across primary and secondary care, within Northern Ireland (NI). It is intended for use by all healthcare professionals involved in the care of these patients.

There will always be exceptions, and some children may be on differing doses, as per their specialist. This is intended as a guide to initial starting doses and recommendation of the preparations to be prescribed.

The indications in the BNF for children (BNFc) for PPIs include:

- gastro-oesophageal reflux disease (GORD)
- acid-related dyspepsia
- prevention or treatment of peptic ulceration (e.g. alongside long term steroids/NSAIDs)
- *H. pylori* eradication regimens
- Zollinger-Ellison syndrome
- fat malabsorption despite pancreatic enzyme replacement in cystic fibrosis

This guideline concentrates on the use of PPIs in GORD. Refer to [BNFc](#) for recommended doses for all other indications. However, the choice of preparation highlighted is relevant for all indications.

## Key points

- Omeprazole dispersible tablets and lansoprazole orodispersible tablets should be prescribed in doses **rounded to the nearest whole / half / quarter tablet** where possible:
  - ⇒ Omeprazole to nearest 5mg
  - ⇒ Lansoprazole to nearest 3.75mg

### Omeprazole dose rounding example:

ROUND DOSES TO NEAREST 5mg  
WHERE POSSIBLE

Weight (kg)	Initial once daily dose **
< 2.5	0.7 to 1.4mg/kg
2.5 to 6.9	5mg (half of a 10mg tablet)
7 to 15	10mg
≥ 15	20mg

### Lansoprazole dose rounding example:

ROUND DOSES TO NEAREST 3.75mg  
WHERE POSSIBLE

Weight (kg)	Initial once daily dose **
3.5 to 7.49	3.75mg (quarter of a 15mg tablet)
7.5 to 14.9	7.5mg (half of a 15mg tablet)
15 to 29.5	15mg
≥ 30	15 to 30mg

\*\* See later for detailed dosing information including maximum daily dosing

- Liquid formulation of omeprazole is only recommended for the following groups of patients:
  - ⇒ Those with a narrow enteral feeding tube (see details below)
  - ⇒ Those with any enteral feeding device that terminates in jejunum
  - ⇒ Those where the dose of omeprazole is less than 5mg
- Generic lansoprazole orodispersible tablets have been found to block enteral feeding tubes. If using lansoprazole via an enteral feeding tube prescribe Zoton® FasTabs
- Generic omeprazole dispersible tablets have been found to block enteral feeding tubes. If using omeprazole via an enteral feeding tube prescribe Losec® MUPS
- A proton pump inhibitor should be prescribed for appropriate indications at the lowest effective dose for the shortest period.
- The need for ongoing treatment should be reviewed regularly to consider continued need, dose optimisation and suitability of formulation. Initial use should be a 4 week trial. Review is particularly important for infant GORD.
- [NICE NG1](#) and [ESPGHAN](#) recommend that after 4 to 8 weeks treatment, a trial off the medication should be attempted.
- Consider a trial of discontinuing PPI if child is still on PPI when weaning.

## Which PPI?

There is evidence for the use of both omeprazole and lansoprazole in children and both are widely used in Paediatrics. BNFC has clear recommended doses for omeprazole and lansoprazole for all ages from birth. Both [BNFC](#) and [Guy's and St Thomas' Paediatric Formulary](#) doses are reflected in this guideline. As with a great deal of prescribing in Paediatrics, their use is often off-label.

Table 1 summarises the available PPI preparations, their paediatric license for GORD, and the current Drug Tariff price. The decision as to which PPI to prescribe ultimately lies with the prescriber.

Esomeprazole 10mg granules sachets are licensed from 1 year of age, but at the time of writing they are not routinely used in NI in Paediatrics and have therefore not been included within this guide.

For more detailed licensing and prescribing information for all indications see the individual [Summary of Product](#) Characteristics (SPCs) and [BNF for children](#) (BNFC).

**There are limitations to the use of licensed oral suspensions of omeprazole (as per Table 1). Within general Paediatrics, orodispersible tablet and capsule formulations of PPIs have been used successfully with little need for alternatives.**

**Table 1**

Product	Paediatric license	Drug Tariff Price <sup>1</sup>
<b>Omeprazole</b>		
Dispersible tablets: 10 mg, 20 mg, 40 mg	Children over 1 year of age and ≥ 10 kg	10mg x 28 £9.30; 20mg x 28 £13.92
Capsules: 10 mg, 20 mg, 40 mg	Children over 1 year of age and ≥ 10 kg	10mg x 28 £1.21 20mg x 28 £0.88
Liquid oral suspension*: 1mg/ml; 10mg/5ml; 20mg/5ml	1mg/ml: Children 1 to 12 months of age; 10mg/5ml and 20mg/5ml: Children over 1 month of age. They are only licensed up to a dose of 1mg/kg once daily (note: BNFC recommends doses of 0.7-3mg/kg daily (dependant on age)).  <b>10mg/5ml oral suspension is the current recommended strength for prescribing on the <a href="#">HSC Agreed list of Paediatric liquid medicines</a></b>	1mg/ml x 75ml £111; 10mg/5ml x 75ml £124; 20mg/5ml x 75ml £234
<b>Lansoprazole</b>		
Orodispersible tablets: 15mg, 30mg	Not licensed in children (used off-label – see above)	15mg x 28 £2.72 (Zoton® FasTabs £2.99), 30mg x 28 £4.66 (Zoton® Fas Tabs £5.50)
Capsules: 15mg, 30mg	Not licensed in children (used off-label – see above)	15mg x 28 £0.85, 30mg x 28 £1.16
Liquid oral suspension	Can be ordered as an unlicensed special (note: there is <b>no Drug Tariff price, therefore cost can vary</b> ). However, lansoprazole suspension is not recommended due to it being unlicensed and varying costs and should therefore not be prescribed. Prices up to £600 x 100ml have been seen in primary care	
*Due to the mint flavouring used in these preparations they have been poorly tolerated in some neonatal and paediatric patients. These preparations also contain 6.95mmol of potassium per 5ml dose.		
<sup>1</sup> Drug Tariff Nov 2024		

## Oral preparations for patients **without** enteral feeding tubes

Age	Weight	Preparation	Dose
Neonate	< 1.7kg	Omeprazole liquid – refer to the <a href="#">HSC Agreed list of paediatric liquid medicines</a> for appropriate product	700 micrograms/kg once daily for 7 to 14 days, then increased if necessary to maximum 2.8mg/kg once daily
	>1.7kg	1st line: omeprazole 10mg dispersible tablets <b>5mg is the lowest measurable dose</b>  If dose <5mg, move to 2 <sup>nd</sup> line option 2nd line: omeprazole liquid – refer to the <a href="#">HSC Agreed list of paediatric liquid medicines</a> for appropriate product Or	700 micrograms/kg once daily for 7 to 14 days, then increased if necessary to maximum 2.8mg/kg once daily <b>Dose MUST be rounded to nearest 5mg for orodispersible tablets</b>
		Lansoprazole 15mg orodispersible tablets <b>3.75mg is the lowest measurable dose</b> <b>If weight &lt; 3.5kg—use omeprazole</b>	0.5 mg/kg to 1mg/kg once daily (max 15mg) <b>Dose MUST be rounded to nearest 3.75mg</b>
PPIs not routinely recommended in neonates: PPIs can sometimes increase the risk of infections and allergies in neonates. They may also reduce the absorption of some nutrients from milk.			
4 weeks up to 1 year		Omeprazole 10mg dispersible tablets <b>5mg is lowest measurable dose</b> Or	700 micrograms/kg to 3mg/kg once daily (max 20mg) <b>Dose MUST be rounded to nearest 5mg</b>
		Lansoprazole 15mg orodispersible tablets <b>3.75mg is the lowest measurable dose</b> <b>If weight &lt; 3.5kg—use omeprazole</b>	0.5 mg/kg to 1mg/kg once daily (max 15mg) <b>Dose MUST be rounded to nearest 3.75mg</b>
1-17 years		<b>1st Line:</b> (if able to swallow capsules) Omeprazole 10mg or 20mg capsules  If cannot swallow capsule move to 2 <sup>nd</sup> line option. <i>See administration information also re opening capsules.</i>  <b>2nd Line:</b> (if not able to swallow capsule) Omeprazole 10mg or 20mg dispersible tablets <b>5mg is the lowest measurable dose</b> or	1 to up to 2 years: 700micrograms/kg to 3mg/kg once daily (max 20mg)  From 2 years: <20kg: 10mg once daily (increased to max 20mg) >20kg: 20mg once daily (increased to max 40mg)  Omeprazole capsules: <b>dose MUST be rounded to 10mg or 20mg</b> Omeprazole dispersible tablets: <b>dose MUST be rounded to nearest 5mg</b>
		Lansoprazole 15mg or 30mg orodispersible tablets <b>3.75mg lowest measurable dose</b>	0.5 mg/kg to 1mg/kg once daily (< 30kg max 15mg; ≥30kg max 30mg) <b>Dose MUST be rounded to nearest 3.75mg</b>

## Preparations for patients **with** enteral feeding tubes

**\* Important point:** Please consider whether a patient with an enteral tube can take medications orally before following this guidance\*

Feeding tube size	Preparation	Dose
≤ 6Fr or any size of jejunal device	Omeprazole liquid – <i>refer to the <a href="#">HSC Agreed list of paediatric liquids</a> for appropriate product</i>	<p><b>Neonates:</b> 700 micrograms/kg once daily for 7 to 14 days, then increased if necessary to max 2.8mg/kg once daily</p> <p><b>From 4 weeks to 2 years:</b> 700 micrograms/kg to 3mg/kg once daily (max 20mg)</p> <p><b>From 2 years:</b> &lt;20kg: 10mg once daily (increased to max 20mg) &gt;20kg: 20mg once daily (increased to max 40mg)</p>
8 Fr+	<p>1st line: omeprazole 10mg dispersible tablets (Losec® MUPS) <b>5mg is the lowest measurable dose</b></p> <p>If dose &lt;5mg, move to 2<sup>nd</sup> line option</p> <p>2nd line: omeprazole liquid – <i>refer to the <a href="#">HSC Agreed list of paediatric liquid medicines</a> for appropriate product</i></p> <p>or</p>	<p><b>4 weeks to 2 years:</b> 700 micrograms/kg to 3mg/kg once daily (max 20mg) <b>Dose MUST be rounded to nearest 5mg for omeprazole orodispersible tablets</b></p> <p><b>From 2 years:</b> &lt;20kg: 10mg once daily (increased to max 20mg) &gt;20kg: 20mg once daily (increased to max 40mg)</p>
	<p>Lansoprazole 15mg orodispersible tablets (Zoton® FasTab®)</p> <p><b>3.75mg is the lowest measurable dose</b> <b>If weight &lt; 3.5kg—use omeprazole</b></p>	<p>0.5 mg/kg to 1mg/kg once daily (&lt; 30kg max 15mg. ≥30kg max 30mg) <b>Dose MUST be rounded to nearest 3.75mg</b></p>
<ul style="list-style-type: none"> <li>• <b>Be aware that administration of other brands / generics differ and can lead to tube blockage</b></li> <li>• Caution is advised with jejunal extensions which can differ in size from the feeding tube in place. Therefore any patient who is receiving omeprazole via a jejunal device, no matter what size the device is – the recommendation is that omeprazole liquid is prescribed.</li> <li>• PPIs are not routinely recommended in neonates: PPIs can sometimes increase the risk of infections and allergies in neonates. They may also reduce the absorption of some nutrients from milk.</li> </ul>		

## Oral administration information

<b>Omeprazole dispersible tablets</b>	<ul style="list-style-type: none"> <li>The 10mg tablets may be halved to give 5mg but must not be divided further</li> <li>Disperse in a small amount of water (e.g. 5 to 10ml) for 5 to 10 minutes and mixed well before administration</li> <li>Proportionate doses CANNOT be administered accurately using the dispersion therefore any doses must be rounded to the nearest 5mg and the tablet should be cut before dispersing in water</li> </ul>
<b>Lansoprazole orodispersible tablets</b>	<ul style="list-style-type: none"> <li>Orodispersible tablets designed to melt in the mouth or disperse in a small amount of water (e.g. 5 to 10ml) or fruit juice</li> <li>The 15mg tablets can be halved to give 7.5mg or quartered to give 3.75mg, using a tablet cutter, but must not be divided further</li> <li>Proportionate doses CANNOT be administered accurately using the dispersion. Therefore any doses should be rounded to the nearest 3.75mg and cut before dispersing in water</li> </ul>
<b>Omeprazole capsules</b>	<ul style="list-style-type: none"> <li>Swallow whole or capsules can be opened and dispersed in water or cold soft foods, e.g. yoghurt, jam or apple puree.</li> <li>Do not mix with milk or carbonated liquids.</li> <li>The enteric coated pellets must not be chewed</li> </ul>

## Enteral feeding tube administration information

<b>Omeprazole dispersible tablets and lansoprazole orodispersible tablets</b>	<ul style="list-style-type: none"> <li>Flush the tube with water (sterile water if &lt;6 months)</li> <li>Place the tablet (or half or quarter tablet) in the barrel of a 20ml syringe</li> <li>Replace the plunger and fill the syringe with 10ml water (sterile water if &lt;6 months)</li> <li>Ensure the tip of the syringe is kept upright to avoid clogging and shake to disperse the granules</li> <li>Attach to the tube and administer the contents of the syringe using a push and pull technique to ensure granules remain suspended</li> <li>Once the dose has been administered, rinse syringe and flush with water (sterile water if &lt;6 months)</li> <li>Flush the tube very well after giving dose, as this medication is prone to blocking tubes</li> </ul>
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## Information leaflets for parents and carers

[Medicines for children](#) have produced leaflets on how to use the following medicines:

- [Omeprazole for gastro-oesophageal reflux disease \(GORD\)](#)
- [Lansoprazole for gastro-oesophageal reflux disease \(GORD\) and ulcers](#)

There are additional information leaflets for omeprazole and lansoprazole administration available on the [NI Formulary](#) website.

## Long term use of PPIs

Adverse effects of PPIs are usually mild and reversible and include headache, diarrhoea, nausea, abdominal pain, constipation, dizziness and skin rashes.

However, long term use of PPIs can result in a variety of serious adverse effects, which again highlights the importance of regular ongoing reviews.

Some of these adverse effects include, increased risk of:

- **bone fracture** (22% increase risk in next 6 years if PPI initiated before 6 months of age)
- **Clostridium difficile/enteric infections/ear infections/respiratory infections including community acquire pneumonia (CAP).** CAP risk doubles and persists for 7 years post exposure
- **acute kidney injury**
- **asthma**
- **reduced absorption of vitamin B12, magnesium, calcium, iron, folate, zinc- hypomagnesemia** (cases after only 3 months of PPI treatment)

## Important safety information highlighted in BNFc

**For all PPIs:**

*MHRA advice: Proton pump inhibitors (PPIs): very low risk of subacute cutaneous lupus erythematosus (September 2015)*

Very infrequent cases of subacute cutaneous lupus erythematosus (SCLE) have been reported in patients taking PPIs. Drug-induced SCLE can occur weeks, months or even years after exposure to the drug.

## Regular reviews

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

## References

1. Guy's and St Thomas' NHS Foundation Trust, Paediatric Formulary app. <https://app.clinibee.com/>
2. Medicines for Children. <https://www.medicinesforchildren.org.uk/>
3. Joint Formulary Committee. British National Formulary for children (online) London: BMJ and Pharmaceutical Press <http://www.medicinescomplete.com> [Accessed 01/06/2024]
4. NHS Greater Glasgow and Clyde Guide. Proton Pump Inhibitor Guideline for Neonates and Paediatrics. <https://www.clinicalguidelines.scot.nhs.uk/media/4038/921-proton-pump-inhibitor-neo-paed.pdf>
5. Electronic medicines compendium (emc) online <https://www.medicines.org.uk/emc>
6. The NEWT Guidelines <https://www.newtguidelines.com/>
7. White R and Bradnam V. Handbook of drug administration via Enteral Feeding Tubes. <https://about.medicinescomplete.com/>
8. NICE Guideline (NG1) Gastro-oesophageal reflux disease in children and young people: diagnosis and management <https://www.nice.org.uk/guidance/ng1>
9. ESPGHAN guidelines 2017. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines. [https://www.espghan.org/knowledge-center/publications/Gastroenterology/2017\\_Pediatric\\_Gastroesophageal\\_Reflux\\_Clinical\\_practice\\_guidelines](https://www.espghan.org/knowledge-center/publications/Gastroenterology/2017_Pediatric_Gastroesophageal_Reflux_Clinical_practice_guidelines)
10. PrescQIPP. Bulletin 267: PPIs - Long term safety and gastroprotection (prescqipp.info) <https://www.prescqipp.info/our-resources/bulletins/bulletin-267-ppis-long-term-safety-and-gastroprotection/>

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