

Paediatric Prescribing Guideline: Proton Pump Inhibitors

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A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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1. Introduction

The aim of this guideline is to standardise prescribing practice of Proton Pump Inhibitors (PPIs) whilst ensuring patients are given appropriate and effective treatments.

This guideline covers the use of PPIs in paediatrics, across UHSussex (UHSx). It is intended for use by all health professionals involved in the care of these patients. UHSx encourage rational use of PPI in the community.

PPIs are indicated for use in patients for:

- Gastro-oesophageal reflux disease (GORD)
- Persistent or significant symptoms of reflux oesophagitis despite other measures
- Prevention or treatment of peptic ulceration (e.g. alongside long term steroids/NSAIDs)
- H. pylori eradication regimens

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

Within general paediatrics, orodispersible tablet and capsule formulations of PPIs have been used successfully with little need for alternatives (see tables below for further advice).

2. Principles

- **Review all patients prescribed PPIs and switch treatment to align with this guidance.**
- **ONLY patients who have an enteral feeding tube or who are under 1 year of age should be on a liquid formulation of Omeprazole.**
- **UHSx will be switching to Omeprazole solution 20mg/5ml (Aclomep®). (see MGC decision).**
- **For patients prescribed Aclomep®, it is expected that primary care will continue treatment with omeprazole 2mg/mL & 4mg/mL suspension (in line with current ICB formulary)**

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3. Formulation and Dosing for patients taking medication orally (without an enteral feeding tube)

Age	Preparation	Dose
Under 1 year	Omeprazole solution 20mg/5mL (Aclomep®)	700micrograms/kg - 2.8mg/kg Maximum dose: 20mg ONCE each DAY
1 year onwards	<p>1st Line: Omeprazole capsules 10mg or 20mg * (capsules can be opened and whole doses given - see administration section).</p> <p>Round the dose 10 or 20mg. If not possible move to 2nd line option</p> <p>2nd Line: Omeprazole dispersible tablets 10mg or 20mg (Losec MUPS®)**</p> <p>Round the dose to the nearest 5mg</p> <p>3rd Line: Lansoprazole orodispersible tablets 15mg or 30mg (Zoton FasTab®)***</p> <p>Round the dose to the nearest 3.75mg</p> <p>OR if significant issues</p> <p>Esomeprazole gastro-resistant granules 10mg (Nexium®)</p>	<p>700micrograms/kg - 3mg/kg Maximum dose: <20kg: 20mg ≥20kg: 40mg ONCE each DAY</p> <p>700micrograms/kg - 3mg/kg Maximum dose: <20kg: 20mg ≥20kg: 40mg ONCE each DAY</p> <p>0.5 mg/kg to 1mg/kg Maximum dose: 30mg ONCE each DAY</p> <p>1 - 11 years (10-19kg): 10mg 1 - 11 years (20kg+): 10 or 20mg 12 - 17 years: 40mg for 4-8 weeks then reduce to 20mg ONCE each DAY</p>
<p>In primary care they use omeprazole suspension. Note all patients on Omeprazole solution 20mg/5mL (Aclomep®) will be switched onto the suspension formulation by the primary care provider</p>		

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4. Formulation and Dosing for patients taking medication via an enteral feeding tube

Please consider whether a patient with an enteral tube can take medications orally before following this guidance.

	Preparation	Dose
Under 1 year	Omeprazole solution 20mg/5mL (Aclomep®)	700micrograms/kg - 2.8mg/kg Maximum dose: 20mg ONCE each DAY
1 year onwards	Esomeprazole GR Granules 10mg (Nexium®)	1 - 11 years (10-19kg): 10mg 1 - 11 years (20kg+): 10 or 20mg 12 - 17 years: 40mg for 4-8 weeks then reduce to 20mg ONCE each DAY
Other options that could be considered. Not recommended for routine use	Omeprazole dispersible tablets 10mg or 20mg (Losec MUPS®)** Round the dose to the nearest 5mg.	700micrograms/kg - 3mg/kg Maximum dose: <20kg: 20mg ≥20kg: 40mg ONCE each DAY
	Lansoprazole orodispersible tablets 15mg or 30mg (Zoton FasTab®)*** Round the dose to the nearest 3.75mg	0.5 mg/kg to 1mg/kg Maximum dose: 30mg ONCE each DAY
In primary care they use omeprazole suspension. Note all patients on Omeprazole solution 20mg/5mL (Aclomep®) will be switched onto the suspension formulation by the primary care provider		

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5. Administration

***Omeprazole dispersible tablets (Losec MUPS®)** can be dispersed in a small amount of water for 5-10 minutes and mixed well before administration.

The 10mg tablets may be halved to give 5mg but must not be divided further.

Proportionate doses CANNOT be administered accurately using the dispersion therefore any **doses must be rounded to the nearest 5mg.**

****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.

*****Lansoprazole orodispersible tablets (Zoton FasTabs®)** are strawberry flavoured orodispersible tablets designed to melt in the mouth. The orodispersible tablets can also be dispersed in a small amount of water or fruit juice.

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.

Proportionate doses CANNOT be administered accurately using the dispersion. **Therefore any doses should be rounded to the nearest 3.75mg.**

6. Omeprazole dispersible tablets (Losec MUPS®) and lansoprazole orodispersible tablets (Zoton FasTabs®) via enteral feeding tubes

(Please be aware that administration of other brands/generics differ and can lead to tube blockage):

1. Flush the tube with water (sterile water if <6 months).
2. Place the tablet (or half or quarter tablet) in the barrel of a 20mL syringe.
3. Replace the plunger and fill the syringe with 10mL water (sterile water if <6 months).
4. Place a cap on the syringe
5. Ensure the tip of the syringe is kept upright to avoid clogging and shake to disperse the granules.
6. Remove cap, attach to the tube and administer the contents of the syringe using a push and pull technique to ensure granules remain suspended.
7. Once the dose has been administered, rinse syringe and flush with water (sterile water if <6 months).
8. Flush the tube very well after giving dose.

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7. Long-term use of proton pump inhibitors (PPIs)

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 *Clostridioides difficile* (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.

References

- Clinibee (Evelina) Omeprazole monograph accessed May 2023
- NHS Greater Glasgow and Clyde (NHSGGC) Proton Pump Inhibitor Guideline for Neonates and Paediatrics version 1
- BNFC online access May 2023
- electronic medicines compendium accessed May 2023
- TAM (Treatments and Medicines) app Highland NHS Proton pump inhibitor (PPI) selection and administration in children