



CLINICAL GUIDELINE

Proton Pump Inhibitor Guideline for Neonates and Paediatrics

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. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

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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Approval Group:	Medicines Utilisation Subcommittee of ADTC

Important Note:

The Intranet version of this document is the only version that is maintained. Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

NHS Greater Glasgow and Clyde – Use of Proton Pump Inhibitors (PPIs) in Neonates and Paediatrics

1. Objectives

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

2. Scope

This guideline covers the use of PPIs in neonates and paediatrics, across primary and secondary care, within NHS Greater Glasgow and Clyde. It is intended for use by all health professionals involved in the care of these patients.

3. Introduction

PPIs are indicated for use in patients for:

- gastro-oesophageal reflux disease that has not responded to other treatments such as feed thickeners, alginates or H₂-receptor antagonists (if supply resumes)
- 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

The need for ongoing treatment should be reviewed regularly and is particularly important for infant GORD.

Licensed suspensions of oral omeprazole are available, however there are limitations to the use of these products (see further advice section below), and these products are not currently recommended for use for paediatric patients in NHSGGC.

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).

4. Oral preparations for Patients without Enteral Feeding Tubes

Please **prescribe by brand** and find additional administration information below (after table). For Aclomep please prescribe as omeprazole solution 20mg/5ml with Aclomep added as pharmacy text.

Weight	Age	Preparation	Dose	Licensing Status
<1.7kg	<6 months	1st Line: Omeprazole solution 20mg/5ml (Aclomep)	700micrograms/kg to 3mg/kg once daily	Unlicensed product
1.7kg - 3.3kg	<6 months	1st Line: Omeprazole dispersible 10mg tablets (Losec MUPS®)* 5mg lowest measurable dose 2nd Line: Omeprazole solution 20mg/5ml (Aclomep)	700micrograms/kg to 3mg/kg once daily (max 10mg) Doses must be rounded to the nearest 5mg for MUPS®	Off label use ¹ Unlicensed product
> 3.3kg - 10kg	Up to 1 year	1st Line: Omeprazole dispersible 10mg or 20mg tablets (Losec MUPS®)* 5mg lowest measurable dose OR Omeprazole 10mg or 20mg capsules if patient has weaned onto solids* 10mg lowest measurable dose 2nd Line (Neonatologists): Omeprazole solution 20mg/5ml (Aclomep) 2nd Line (Paediatricians/GPs): Lansoprazole orodispersible 15mg tablets (Zoton FasTab®)* 3.75mg lowest measurable dose	700micrograms/kg to 3mg/kg once daily (max 20mg) Doses must be rounded to the nearest 5mg for MUPS® or the nearest 10mg for capsules 0.5 mg/kg to 1mg/kg once daily (max 11.25mg) Doses must be rounded to the nearest 3.75mg for Zoton FasTabs®	Off label use ¹ Off label use ¹ Unlicensed product Off label use ¹

> 10kg	1 – 17 years	1st Line: Omeprazole 10mg or 20mg capsules* 2nd Line: Omeprazole dispersible 10mg or 20mg tablets (Losec MUPS®)* 3rd Line: Lansoprazole orodispersible 15mg or 30mg tablets (Zoton FasTab®)* 3.75mg lowest measurable dose OR Esomeprazole 10mg gastro-resistant granules (Nexium®)	<20kg: 10mg once daily (increased to max 20mg) >20kg: 20mg once daily (increased to max 40mg) 0.5 mg/kg to 1mg/kg once daily (weight up to 30kg, max 15mg) (weight 30kg+, max 30mg) 1 - 11 years (10-19kg): 10mg once daily 1 - 11 years (20kg+): 10 or 20mg once daily 12 - 17 years: 40mg once daily for 4-8 weeks then reduce to 20mg once daily	Licensed product Licensed product Off label use ¹ Licensed product

* See below for administration information for omeprazole MUPS®, omeprazole capsules and lansoprazole FasTabs®

1. Off label means the medication is being used in a way that is different to the product's license, e.g. use outside the licensed age range.

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 (off label) to give 5mg but must not be divided further. The tablets are not scored but snap in half easily, if there are difficulties splitting the tablet a tablet cutter can be provided. 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, fruit juice or soft foods e.g. 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.

5. Preparations for Patients with Enteral Feeding Tubes

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

Caution is advised with jejunal extensions which can differ in size from the feeding tube in place. Brand prescribing is advised.

For Aclomep please prescribe as omeprazole solution 20mg/5ml with Aclomep added as pharmacy text.

Feeding Tube Bore	Preparation	Dose	Licensing Status
≤ 6Fr or jejunal extension in situ	1st Line: Omeprazole solution 20mg/5ml (Aclomep)	700micrograms/kg to 3mg/kg once daily (< 1 year, max 20mg) (2 – 17 years: 10-19kg, max 20mg) (2 – 17 years: 20kg+, max 40mg)	Unlicensed product
8 Fr +	1st Line: Omeprazole dispersible 10mg or 20mg tablets (Losec MUPS®) 5mg lowest measurable dose	700micrograms/kg to 3mg/kg once daily Doses must be rounded to the nearest 5mg for MUPS® (< 1 year, max 20mg) (2 – 17 years: 10-19kg, max 20mg) (2 – 17 years: 20kg+, max 40mg)	Off label use ¹
	2nd Line: Lansoprazole orodispersible 15mg or 30mg tablets (Zoton FasTab®) 3.75mg lowest measurable dose	0.5 mg/kg to 1mg/kg once daily (weight up to 30kg, max 15mg) (weight 30kg+, max 30mg) Doses must be rounded to the nearest 3.75mg for Zoton FasTabs®	Off Label use ¹
	3rd Line: Esomeprazole 10mg GR Granules (Nexium®)	1 - 11 years (10-19kg): 10mg once daily 1 - 11 years (20kg+): 10 or 20mg once daily 12 - 17 years: 40mg once daily for 4-8 weeks then reduce to 20mg once daily	Off label <1 year and <10kg Licensed for 6Fr +

1. Off label means the medication is being used in a way that is different to the product's license, e.g. use outside the licensed age range.

Administration of 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. Ensure the tip of the syringe is kept upright to avoid clogging and shake to disperse the granules.
5. Attach to the tube and administer the contents of the syringe using a push and pull technique to ensure granules remain suspended.
6. Once the dose has been administered, rinse syringe and flush with water (sterile water if <6 months).
7. Flush the tube very well after giving dose, as this medication is prone to blocking tubes.

6. Further Advice

Licensed suspensions of oral omeprazole 10mg/5ml and 20mg/5ml are available from Rosemont Pharmaceuticals, however due to the mint flavouring used in these preparations they have been poorly tolerated in neonatal and paediatric patients. These preparations also contain 6.95mmol of potassium per 5ml dose. They are only licensed up to a dose of 1mg/kg once daily which limits dose escalation as the BNF for children recommends doses of 0.7-3mg/kg daily (dependant on age). **Therefore these products are not recommended for use for paediatric patients in NHSGGC at present.**

Aclomep omeprazole solution 20mg/5ml is an unlicensed medicine. Aclomep omeprazole oral solution 20mg/5ml appears on the pre-approved guide price list for commonly requested unlicensed medicines, which provides a maximum cost that the Board will approve without prior authorisation. **Aclomep should be used in line with restricted indications as per this guidance.**

If a prescriber is unsure about administration of a PPI or would like further advice for an individual patient please contact one of the paediatric pharmacists at the Royal Hospital for Children, Glasgow (via Pharmacy 2nd floor medicines management room 0141 451 4471).