

Use of Proton Pump Inhibitors in Neonates and Paediatrics



TARGET AUDIENCE	Board-wide
PATIENT GROUP	All Neonates and Paediatric Patients requiring a Proton Pump Inhibitor

Clinical Guidelines Summary

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

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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 and treatment of peptic ulceration (e.g. alongside long term steroids/NSAIDs)
- H pylori eradication regimens
- Fat malabsorption despite pancreatic enzyme replacement therapy in cystic fibrosis

Before initiating treatment with a proton pump inhibitor consideration should be given to alternative therapies (gaviscon, carobel) and diet, including milk volume in infants.

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

Licensed oral omeprazole suspension is available in 2 strengths, 10mg/5ml and 20mg/5ml, from Rosemont Pharmaceuticals, however there are limitations to the use of these products. Due to their viscosity and the mint flavouring used in these preparations they have been poorly tolerated in neonatal and paediatric patients. They also contain 6.95mmol of potassium per 5ml dose and 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 NHSL at present.

Oral preparations for all Neonatal & Paediatric Patients without Enteral Feeding Tubes

Preparation		Licensing Status	Dose
1 st line	LOSEC [®] (Omeprazole) 10mg MUPS MUPS doses must be prescribed in multiples of 5mg. Do not disperse and give a proportion of the volume as dose accuracy cannot be guaranteed.	Off Label	700micrograms/kg to 3mg/kg once daily. ≤ 1 year, max 3mg/kg up to 20mg daily 2-17 years, 10-19kg, max 20mg daily 2-17 years, 20kg +, max 40mg daily
2 nd line	ACLOMEP [®] (Omeprazole) 20mg/5ml	Unlicensed product	

Please Prescribe by **BRAND**. Children > 15kg, able to swallow solid dosage forms and on a dose which is a multiple of 10mg can be prescribed omeprazole capsules.

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Oral preparations for all Neonatal & Paediatric Patients with Enteral Feeding Tubes

Age	Preparations		Licensing Status	Dose
<1 year	ACLOMEP [®] (Omeprazole) 20mg/5ml		Unlicensed product	
>1 year and 8Fr+ (Fr = French Size medical tubing unit of measurement)	1 st line	LOSEC [®] (Omeprazole) 10mg MUPS MUPS doses must be prescribed in multiples of 5mg. Do not disperse and give a proportion of the volume as dose accuracy cannot be guaranteed.	Off Label	700micrograms/kg to 3mg/kg once daily. ≤ 1 year, max 3mg/kg up to 20mg daily 2-17 years, 10-19kg, max 20mg daily 2-17 years, 20kg +, max 40mg daily
	2 nd line	ACLOMEP [®] (Omeprazole) 20mg/5ml	Unlicensed product	
	3 rd line	ZOTON [®] (Lansoprazole) 15mg FAST TABS FAST TAB doses must be prescribed in multiples of 3.75mg. Do not disperse and give a proportion of the volume as dose accuracy cannot be guaranteed.	Off Label	0.5mg/kg to 1mg/kg once daily Weight up to 30kg, max 15mg daily Weight 30kg+, max 30mg daily

Caution is advised with jejunal extensions which can differ in size from the feeding tube in place. Please Prescribe by **BRAND** as ADMINISTRATION OF OTHER BRANDS/GENERICIS DIFFER AND CAN LEAD TO TUBE BLOCKAGE.

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Further information on the recommended Proton Pump Inhibitors

Omeprazole dispersible tablets (Losec MUPS®)

- Can be dispersed in a small amount of water (for example, 5mg in 5ml or 10mg in 10ml) and given after 5-10 minutes
- The 10mg tablets may be halved to give 5mg but must not be divided further
- **Proportionate doses CANNOT be administered accurately using the dispersion and taking proportion**
- Any doses must be rounded to the nearest 5mg.

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 and taking proportion**
- Any doses must be rounded to the nearest 3.75mg.

Preparations for Patients with Enteral Feeding Tubes

Administration of omeprazole dispersible tablets (Losec MUPS®) and lansoprazole orodispersible tablets (Zoton FasTabs®) via enteral feeding tubes

1. Flush the tube with water (sterile water if <12months)
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 <12months)
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 <12months)

Flush the tube very well after giving dose, as this medication is prone to blocking tubes

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References/Evidence

- Proton Pump Inhibitor Guideline for Neonates and Paediatrics – NHS Greater Glasgow and Clyde May 2021. Referenced with Permission
- Summary of Product Characteristics - Omeprazole 2 mg/ml, Powder for Oral Suspension Rosemont Pharmaceuticals Limited <https://www.medicines.org.uk/emc/product/11031/smpc#gref> (Accessed: May 2023).
- Paediatric Formulary Committee. BNF for Children <https://bnfc.nice.org.uk/> (Accessed: May 2023).
- Summary of Product Characteristics - Losec MUPS Tablets 10mg Neon Healthcare Ltd <https://www.medicines.org.uk/emc/product/1493/smpc> (Accessed: May 2023).
- Aclomep Product Specification provided by Aclardian Ltd
- Summary of Product Characteristics - Zoton FasTab 15 mg Pfizer Limited <https://www.medicines.org.uk/emc/product/1714/smpc> (Accessed: May 2023).
- Handbook of drug administration via enteral feeding tubes (3rd ed, 2018)

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Appendices

1. Governance information for Guidance document

Lead Author(s):	Lynsay McAulay & Jacqueline Rooney
Endorsing Body:	Paediatric and Neonatal Clinical Directors
Version Number:	1
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Responsible Person (if different from lead author)	

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CHANGE RECORD			
Date	Lead Author	Change	Version
		<i>e.g. Review, revise and update of policy in line with contemporary professional structures and practice</i>	1
			2
			3
			4
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