

Hertfordshire & West Essex - prescribing guidelines for Proton Pump Inhibitor (PPI) use in paediatric patients

Joint guidance for primary and secondary care

1. Purpose

To provide guidance on safe, cost effective PPI prescribing in neonatal and paediatric patients.

2. 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

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.

3. Treatment summary

Lansoprazole is not licensed for use in children (British National Formulary for Children. However, the use of lansoprazole in paediatrics is common practice nationally ([Medicines for Children, 2014](#); [National Health Service, 2018](#))

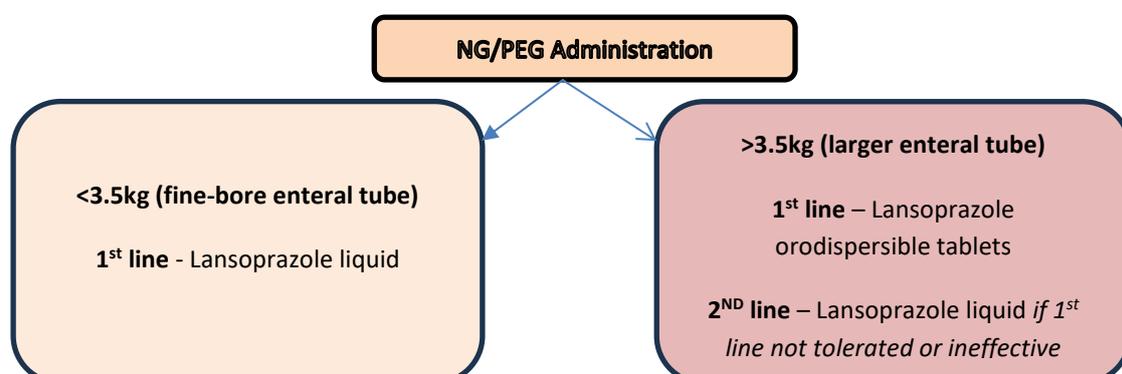
Healthcare professionals may have more responsibility to accurately prescribe an unlicensed medicine or an off-label medicine than when they prescribe a medicine within the terms of its licence. ([Drug Safety Update](#))

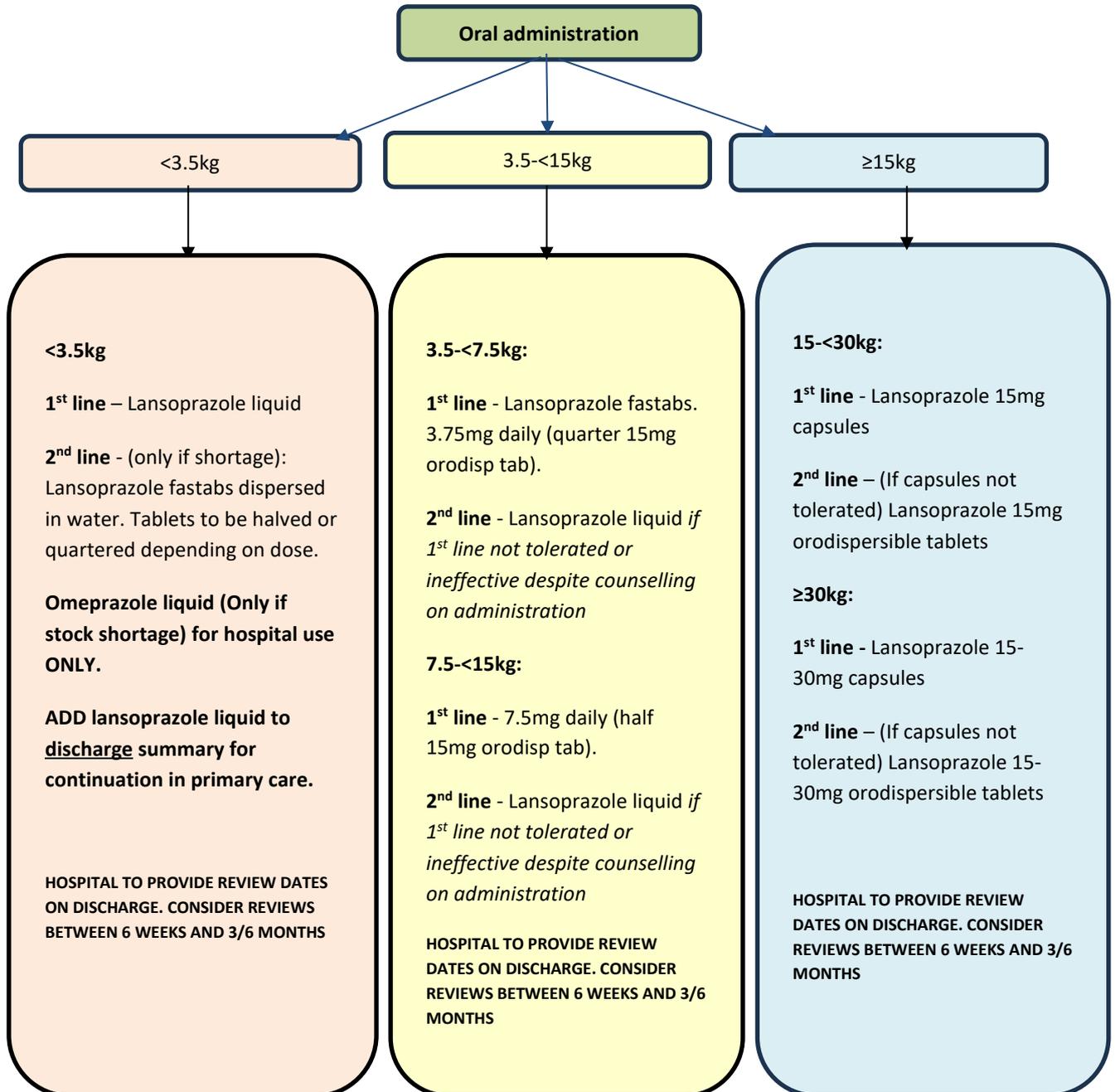
Recommendation of local agreed PPI of choice in paediatrics and enteral feeding

Omeprazole liquid (licensed and specials): RED, recommended for **restricted** prescribing in hospital only

Lansoprazole orodispersible tablets and capsules: GREEN – recommended in primary and secondary care

Lansoprazole liquid (specials): RESTRICTED use in babies <3.5kg and rarely in older children when orodispersible tablets and capsules are not suitable





4.0 Dosing

4.1 Oral administration

Lansoprazole - dosage and administration information.¹ (Refer to BNFC for full information)

Child (body-weight under 30kg): 0.5 – 1 mg/kg (max 15mg) once daily in the morning

Child (body-weight 30kg and over): 15 – 30 mg once daily in the morning

For doses of 15mg or 30mg where the child is able to swallow capsules – use the appropriate strength of the capsule.

Dose schedules are as follows:

Weight	Dose		Counselling
< 3.5kg	0.5-1mg/kg	Lansoprazole liquid (1 st line)	Give 5mg/5ml liquid in an oral syringe
3.5kg – <7.5kg 7.5kg – <15kg	3.75mg	Lansoprazole orodispersible tablets (1 st line)	Use a 15mg orodispersible tablet and ¼ (for 3.75mg dose) or ½ (for 7.5mg dose) the tablet using a tablet splitter. Discard the remaining tablet fragments. <ul style="list-style-type: none"> Place the tablet fragment in the barrel of a 5ml oral syringe, insert plunger and draw up 5ml water. Shake the syringe to disperse the tablet fragment, which will form micro-beads in a milky liquid. Do not crush the micro-beads as they contain the drug and will not dissolve. Give the full volume of micro-beads in liquid immediately. Refill the syringe with 3ml water, shake and give the remaining micro-beads so that the full dose is given.
	7.5mg	Give 5mg/5ml lansoprazole liquid	
		Lansoprazole liquid (2 nd line) – <i>if 1st line not tolerated or ineffective despite counselling on administration</i>	Give 5mg/5ml liquid as appropriate in an oral syringe
15kg – <30kg ≥30kg	15mg	Lansoprazole capsules (1 st line)	Swallow capsule whole or empty contents onto a spoonful of soft, cold food and give immediately
	15-30mg	Lansoprazole orodispersible tablets (2 nd line)	Use a 15mg or 30mg orodispersible tablet dissolved on tongue or <ul style="list-style-type: none"> Place the tablet in the barrel of a 5ml or 10ml oral syringe and draw up 5ml water (15mg dose) or 10ml water (30mg dose). Shake to disperse the tablet, which will form micro-beads in a milky liquid. Do not crush the micro-beads as they contain the drug and will not dissolve.

		<ul style="list-style-type: none"> Give the full volume of micro-beads in liquid immediately. Refill the syringe with 3ml water (15mg dose) or 5ml water (30mg dose), shake and give the remaining micro-beads.
	Lansoprazole liquid (3 rd line) - <i>if 2nd line not tolerated or ineffective despite counselling on administration</i>	Give 30mg/5ml liquid as appropriate in an oral syringe

For **oral administration**, lansoprazole orodispersible tablets can either be placed on the tongue, allowed to **disperse** and swallowed, or may be swallowed whole with a glass of water. Alternatively, some children prefer to have their dose dispersed in small amount of water and administered orally using an oral/enteral syringe.

Note: If only a portion of a tablet is administered do not keep the remainder of the tablet to use for the next dose. A new tablet should be used for each dose.

Children who weigh greater than 3.5kg:

- If unable to swallow capsules and/or where the dose can be given as a portion of an orodispersible tablet (by using a tablet cutter) – use lansoprazole orodispersible tablets. Lansoprazole orodispersible tablets do not form an even dispersion in water so cannot be “part dosed” by dissolving in water and giving an aliquot, nor are they scored.
- If not tolerated/issues with administration, carry out a counselling check to ensure that administration instructions have been followed.
- If still not tolerated after counselling check, lansoprazole 5mg/5ml for doses <15mg or 30mg/5ml liquid for doses >15mg can be issued.

Children who weigh less than 3.5kg:

- Lansoprazole 5mg/5ml oral liquid (alcohol-free and sugar-free) is first line. These are specials (unlicensed medicinal products). Use most appropriate strength based on dose.
- If there are stock issues with the liquid specials in primary care, refer to appendix 1.
- If this is not tolerated or there are stock issues with lansoprazole liquid, then omeprazole liquid can be given. **However, use must be restricted to hospital only. On discharge, the TTO comments section/discharge letter must instruct the GP to switch to lansoprazole liquid for use in primary care. The dose in mg and mg/kg must be clearly stated on the TTO.**

4.2 NG/PEG fed patients

Weight	Dose	Counselling
Patients with enteral tube ≤ 8Fr	Lansoprazole 5mg/5ml oral liquid (alcohol-free and sugar-free) is first line. These are specials (unlicensed medicinal products). Use most appropriate strength based on dose.	Give 5mg/5ml liquid as appropriate in an enteral syringe
Patients with enteral tube > 8Fr	Lansoprazole orodispersible tablets Zoton® (appropriate strength to be given) (1 st line)	As for oral syringe directions according to weight banding above BUT: <ul style="list-style-type: none"> Flush feeding tube with water before and after giving. Use push-pull technique to flush medication.
	Lansoprazole 5mg/5ml or 30mg/5ml oral liquid (alcohol-free and sugar-free) (2 nd line) - <i>if 1st line not tolerated or ineffective despite counselling on administration</i>	

- Zoton (lansoprazole) Fastabs® and lansoprazole orodispersible tablets are licensed for administration via nasogastric feeding tubes.
- Zoton (lansoprazole) Fastabs® contain micro-granules which are very small approximately 0.33mm in diameter and therefore suitable for NG tubes.
- For administration of lansoprazole orodispersible tablets via **larger enteral tubes (>8Fr)**. Enteral feeds should be stopped 30 minutes before administration and tubes flushed well. Mix the whole, halved, or quartered tablet with a

small amount of water (as per PIL). Administer all the solution to ensure that all the microgranules which appear are administered. Do not crush the microgranules. Ensure the tube is flushed well with water and the enteral feed is not restarted until 30 minutes following administration.²

- **As an expensive and unlicensed formulation, lansoprazole oral liquid must be reviewed regularly for appropriateness, particularly on discharge.** Guidance will be reviewed in light of price changes.
- **Once a baby is switched to a larger enteral tube and PPI therapy is still warranted, therapy should be changed to lansoprazole orodispersible tablets.**
- If there are stock issues with the liquid special in primary care, refer to appendix 1.

5. Additional information

5.1 Interactions

The intake of food with lansoprazole slows down the absorption and decreases the bioavailability by about 50%; it is, therefore recommended that lansoprazole is taken 30 minutes before meals.³

5.2 Side effects as listed in the BNFC for all PPIs

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

5.3 Hospital discharge – Treatment plan

- **Discharge letters:**
 - Lansoprazole liquid with equivalent dosing should be added as the PPI of choice to all discharge letters/TTO comments sections where patients have been taking omeprazole liquid in hospital.
 - All other lansoprazole formulations (capsules and orodispersible tablets) should include clear dosage instructions in discharge letter and support with administration, see below
 - Hospital to provide review dates on discharge. Consider reviews between 6 weeks and 3/6 months.
 - Signpost parents to posters with QR codes with counselling information to aid with accurate administration procedure. For ease of upload on to phone.
- Where appropriate, tablet cutters should be provided by the Trust and parents/patients should be given verbal counselling around administration of lansoprazole orodispersible tablets.

References

1. BNF for Children - <https://www.medicinescomplete.com> Accessed November 2021
2. NEWT guidelines – Lansoprazole (2018) - <http://newtguidelines.com/> Accessed November 2021
3. Summary of Product Characteristics – Lansoprazole 15mg Orodispersible Tablets (Mylan) (2018) - <https://www.medicines.org.uk/emc/product/4395/smpc#POSOLOGY>. Accessed November 2021
4. East of England PPI Paed guidance. Accessed December 2024
5. Drug Safety Update: [Off-label or unlicensed use of medicines: prescribers' responsibilities - GOV.UK](#)
6. Medicines for Children: <https://www.medicinesforchildren.org.uk/medicines/lansoprazole-for-gastro-oesophageal-reflux-disease-gord-and-ulcers/>:
7. National Health Service, 2018: [Lansoprazole: medicine to lower stomach acid - NHS](#)

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Version	v3.0 updated to include decision for omeprazole liquid and enable use of lansoprazole liquid in older children when orodispersible tablets and capsules are not suitable v2.0 Harmonisation of West Essex guidance and HMMC guidance, updates include: • Rebadged from HVCCG, ENHCCG and WECCG to HWE ICB V1.0 November 2021 (Hertfordshire Medicines Management Committee) and February 2022 (West Essex Medicines Optimisation Programme Board)
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