Sheffield Children's NHS
NHS Foundation Trust

Prescribing and Administration of Oral/Enteral Proton Pump Inhibitors (PPIs) and H_2 Antagonists

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Purpose

To provide guidance on the prescribing and administration of oral/enteral proton pump inhibitors (PPIs) and H_2 antagonists.

Intended Audience

This guideline is for use by healthcare professionals at Sheffield Children's NHS Foundation Trust that may prescribe and administer PPIs and/or H_2 antagonists.

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1. Introduction

This guideline facilitates the prescribing and administration of PPIs and H_2 antagonists to patients requiring gastric acid suppressing treatment.

2. Guideline Content

Indications for gastric acid suppressing medicines include treatment of gastro-oesophageal reflux disease, where simple measures have failed, and gastro-protection (e.g., in patients taking long courses of high dose oral steroids or regular NSAIDs).

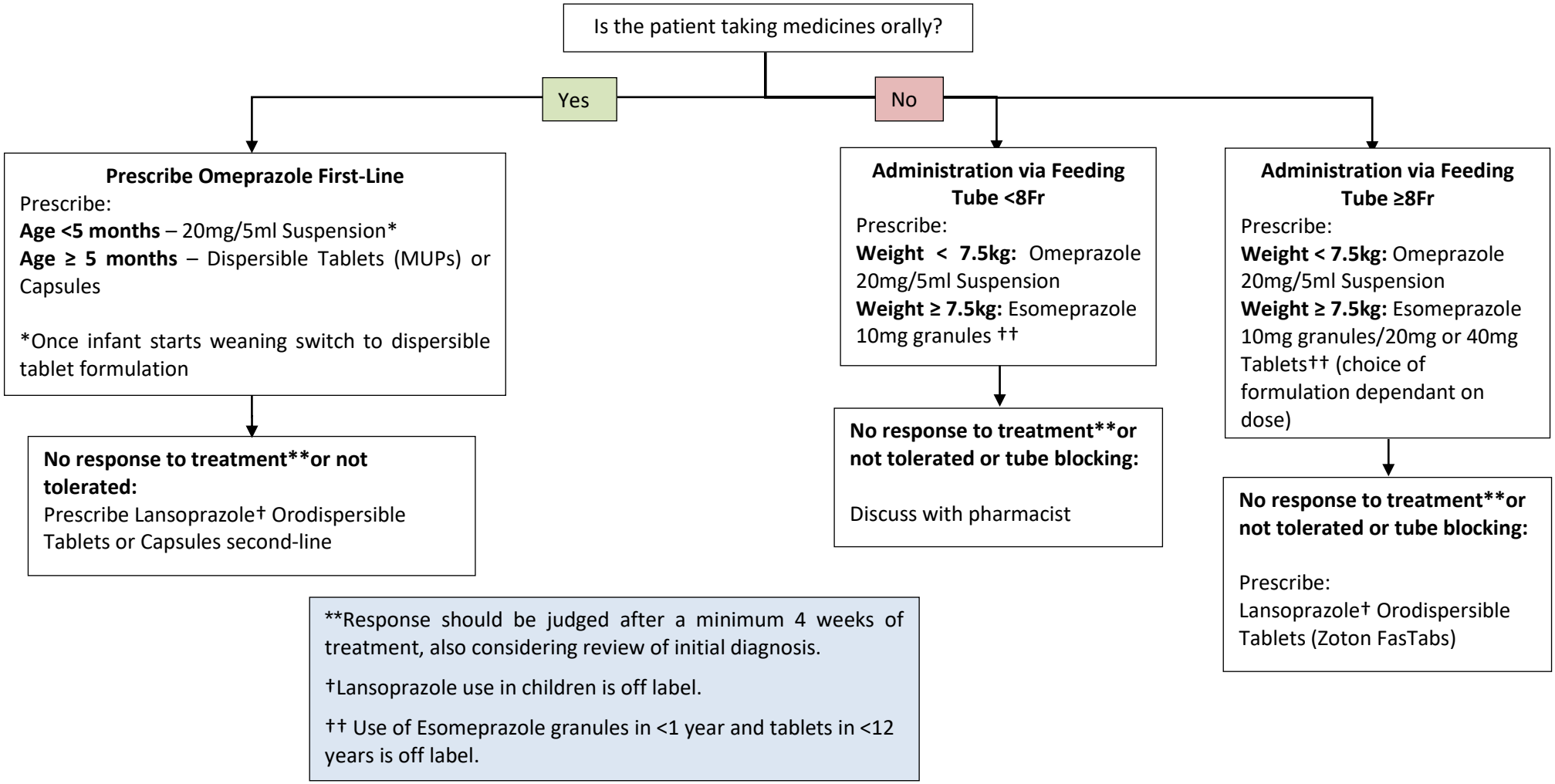
Where gastric acid suppressing treatment is indicated, PPIs are the first-choice drugs. Three oral PPIs are available at Sheffield Children's Hospital.

Omeprazole	The choice of PPI depends on the age and weight of the child and route of administration.
Lansoprazole	
Esomeprazole	

See algorithm below to aid selection of an appropriate PPI.

If PPIs are contraindicated, not tolerated or ineffective a H_2 antagonist can be prescribed second-line. All oral ranitidine preparations are currently unavailable. If a H_2-receptor antagonist needs to be added to treatment famotidine or cimetidine may be used.

Algorithm for Prescribing Proton Pump Inhibitors



**Response should be judged after a minimum 4 weeks of treatment, also considering review of initial diagnosis.

†Lansoprazole use in children is off label.

†† Use of Esomeprazole granules in <1 year and tablets in <12 years is off label.

Recommended Doses:

Omeprazole:
Dispersible tablets: 10mg, 20mg
Capsules: 10mg, 20mg
Oral suspension 20mg/5ml

Age/Weight of Child	Initial Dose	Usual Maximum Dose
Neonate	700 micrograms/kg OD	2.8 mg/kg/day
≥ 1 month: < 5 kg	500 micrograms/kg BD	3.5 mg/kg/day (max 20mg/day)
≥ 1 month: 5 kg – <10 kg	5mg* OD or 2.5mg BD	
≥ 1 month: 10 kg – <20 kg	10mg OD or 5mg* BD	
≥ 1 month: weight ≥ 20 kg	20 mg OD or 10mg BD	3.5 mg/kg/day (max 40mg/day)

* Can use half a 10mg dispersible tablet for oral dose. Round doses to the nearest half a tablet.

Higher starting doses may be required for treatment of peptic ulcer disease and Zollinger-Ellison syndrome.

Infants tend to benefit from a twice daily dosing regime, due to feeding patterns affecting stimulation of gastric acid secretion.

Note: For the treatment of GORD, Omeprazole dispersible tablets and capsules are licensed for use children aged ≥1 year, weighing ≥10kg. Omeprazole suspension is licensed for use in infants and children aged ≥1 month.

Administration:
Oral dispersible tablets do not disperse evenly in water. To administer a fraction of a tablet (e.g., half) the tablet should be cut with tablet splitter to obtain the required dose. Tablets can be dispersed in water and if necessary mixed with a small amount of fruit juice, apple sauce or yoghurt immediately prior to administration. Parents should be advised that when dispersing tablets, the beads will not dissolve. The beads should not be crushed as this will render the drug inactive.

The capsules can be opened, and the contents mixed with a small amount of soft food such as yoghurt, honey or jam.

Adminsitration via enteral feeding tubes (smaller than 8Fr / neonates & infants <7.5kg)
Use omeprazole oral suspension.

(Dispersed tablets may block fine-bore feeding tubes. They should be avoided in feeding tubes <12Fr).

Esomeprazole:
Granules for suspension: 10mg
Tablets: 20mg,40mg

Neonates & Infants weighing < 7.5kg: Use Omeprazole

Age/Weight of Child	Dose	Maximum Dose
> 1 month: ≥ 7.5kg	10mg OD	3.3mg/kg/day (max 40mg)
1 – 11 years: 10-19 kg	10 mg OD	
1 – 11 years: ≥ 20 kg	10 mg to 20 mg OD	
≥ 12 years	20 mg to 40 mg OD*	40mg BD

Note: Licensed for max 8 weeks treatment in children aged 1 -11 years. Prolonged use and use in infants < 1 year would be off label.

Tablets are licensed for children >12 years and can be dispersed in water for administration via a feeding tube size 8Fr and greater.

Administration via enteral feeding tubes:
Granules for suspension (6Fr or larger)

1. Stop the enteral feed.
2. Flush the enteral feeding tube with water.
3. Add the contents of sachet(s) to water. Use 15ml for 10mg dose and 30ml for 20mg dose.
4. Stir.
5. Leave for a few minutes to thicken
6. Stir again.
7. Administer via the gastric tube within 30 minutes of reconstitution.
8. Refill the syringe with water, shake and flush any remaining contents down the enteral feeding tube.

Gastro-resistant tablets (8 Fr or larger):

1. Stop the enteral feed.
2. Put the tablet into an appropriate syringe and fill the syringe with approximately 25ml water and approximately 5ml air. (In some cases, dispersion in 50ml water is needed to prevent the pellets from clogging the tube).
3. Immediately shake the syringe for approximately 2 minutes to disperse the tablet.
4. Hold the syringe with the tip up and check that the tip has not clogged.
5. Attach the syringe to the tube whilst maintaining the above position.
6. Shake the syringe and position it with the tip pointing down. Immediately inject 5–10ml into the tube. Invert the syringe after injection and shake (the syringe must be held with the tip pointing up to avoid clogging of the tip).
7. Turn the syringe with the tip down and immediately inject another 5–10ml into the tube. Repeat this procedure until the syringe is empty.
8. Fill the syringe with 25ml of water and 5ml of air and repeat step 5 if necessary to wash down any sediment left in the syringe (In some cases 50ml water is needed).
9. Flush with recommended volume of water.

Non-adherence to the methods described can lead to blockage of the feeding tube

Lansoprazole:

Orodispersible tablets: 15mg, 30mg
Capsules: 15mg, 30mg

Neonate: Use Omeprazole / Contact pharmacy

Infant/Child weight	Dose	Usual Maximum Dose
<3.5 kg	Use omeprazole / Contact pharmacy	N/A
3.5 kg to 5 kg	3.75 mg OD (use quarter of 15mg tablet)	< 1 year of age: 2mg/kg/day* 1-11 years of age: 3mg/kg/day* (max 30mg) ≥ 12 years: 30mg/day
5 kg to 10 kg	7.5 mg OD (use half of 15 mg tablet)	
10 kg to 30 kg	15 mg OD	
> 30 kg	15-30 mg OD	

*Round doses to nearest quarter of tablet.

Higher starting doses (e.g. double doses) may be required for treatment of peptic ulcer disease and Zollinger-Ellison syndrome.

Note: Licensed for use in adults. Use in children is off label.

Administration:
Oral dispersible tablets do not disperse evenly in water. To administer a fraction of a tablet (e.g., quarter or half) the tablet should be cut with tablet splitter to obtain the required dose, which can then be administered, either dispersed in the mouth or dispersed in water first. Parents should be advised that when dispersing tablets, the beads will not dissolve. The beads should not be crushed as this will render the drug inactive.

Note: Dispersing whole tablets in water and giving a proportion leads to inaccurate dosing. Also, the tablets must not be crushed prior to dispersing.

Administration via enteral feeding tubes (8 Fr or larger – Zoton® brand only)

1. Stop the enteral feed.
2. Flush the enteral feeding tube with water.
3. Place an orodispersible (or proportion of) tablet in barrel of the oral syringe and add 5-10ml water.
4. Allow the tablet to disperse, shaking if necessary.
5. Flush the medication dose down the feeding tube using a push-pull technique to keep granules suspended.
6. Flush the enteral feeding tube.

Note: Zoton® Fastabs can be administered via a feeding tube size 8Fr or greater. The minimum size of feeding tube for different generic versions varies. Therefore, the brand should be specified for feeding tube administration to ensure continuity of supply. Pharmacy can be contacted for advice.

H_2-Receptor Antagonists:

Famotidine:

Not recommended in pre-term neonates.

Age	Dose	Maximum Dose
< 3 months	0.5mg/kg OD	1mg/kg OD
> 3 months: <10kg	0.5 mg/kg BD	1mg/kg BD
> 3 months: 10 kg to < 40kg	0.5mg/kg BD	1mg/kg BD Round dose to nearest 10mg
> 3 months: ≥ 40kg	20mg BD	40mg BD

Available as 20mg and 40mg tablets and 25mg/5ml unlicensed liquid special.

Where possible, doses should be rounded to the nearest 10mg (half a 20mg tablet). For doses less than 10mg an oral suspension can be ordered.

Note: Licensed for use in adults. Use in children is off label.

Administration:
Tablets (or proportion of a tablet) can be crushed and dispersed in water for administration.

Cimetidine:

Age	Dose
< 1month	Not suitable
1 month to <5 years	20mg/kg/day in 3-4 divided doses
> 5 years	20-40mg/kg/day in 3-4 divided doses (max 400mg/dose)

Available as 200mg/5ml oral solution

Propylene Glycol Content:
Cimetidine oral solution contains 500mg/5ml propylene glycol. Propylene glycol is potentially toxic in patients who are unable to adequately metabolise and eliminate it (e.g. neonates, young children and patients with renal failure). The current daily recommended limits for propylene glycol in children are as follows:

< 1month = 1mg/kg/day
1 month to 5 years = 50mg/kg/day
> 5 years = 500mg/kg/day

Cimetidine is therefore not suitable for neonates. The dose above for infants and children aged 1 month to 5 years represents the maximum recommended daily limit of propylene glycol. Therefore, care is need if the child is on other medicines containing propylene glycol. Contact pharmacy for advice.

Interactions:
Cimetidine is a CYP450 enzyme inhibitor and therefore may interact with other medicines. See manufacturer's information, BNFC or contact pharmacy for advice.

3. References

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