V1.2 Last reviewed: December 2021 Review date: December 2024

Algorithm for the review of children and young people taking Omeprazole liquid long term

Why is the medication prescribed? Does the patient still need to be on treatment?

NICE NG1 & ESPGHAN recommend that after 4 to 8 weeks treatment, a trial off the medication should be attempted.

Consider stopping*/reducing the dose if:

- Indication still unknown
- Started for infant reflux and patient now eating some solids
- Gastro-oesophageal reflux disease (GORD) treated for 4-8 weeks (oesophagitis healed, symptoms controlled)
- Completed Helicobacter pylori eradication (in combination with antibiotics)
- Symptom-free for over 3 months
- Started as cover for NSAID/steroid/antiplatelet which is now stopped
- * If patient has been on omeprazole for >6 months, reduce dose over 2-4 weeks before stopping to reduce risk of rebound symptoms.

Treatment **should not be stopped** if the child has been diagnosed with:

- Benign gastric ulcer
- Duodenal ulcers
- On-going, uncontrolled GORD
- Acid related dyspepsia
- Zollinger-Ellison Syndrome
- Eosinophilic oesophagitis

COULD the medicine be given by mouth? Advice on how to teach a child to

swallow solid dosing forms is available on medicinesforchildren.org.uk.

- Previous dystonic crises/status dystonicus
- Fat malabsorption despite pancreatic enzyme replacement therapy in cystic fibrosis
- Gastro-protection whilst coprescribed a potentially ulcerogenic medicine: NSAID; antiplatelets; anticoagulants; corticosteroids; SSRIs; NSAID + SSRIS and/or aspirin.
- Barrett's oesophagus
- Severe oesophagitis
- History of bleeding GI ulcer

Recommend reducing the dose

Stop treatment and monitor for return of symptoms.

Continue treatment but optimise formulation choice

Are medicines administered via a feeding tube?

Monitor at 2-4 weeks & at 12 weeks for: heartburn, dyspepsia, regurgitation, epigastric pain, loss of appetite, weight loss, and agitation. Advise parents / carers to contact the GP if the symptoms reoccur before the review date.

<10kg via tube

Switch to:
Omeprazole oral
suspension^{L1M} SF and
dose as per <u>BNF-c</u>
20mg/5ml strength
preferred

Note that dispersible tablets likely to block tubes.

Child Weight

Obtain weight at the time of review and consistently at every review.

10-20kg via tube

Switch to: Esomeprazole 10mg sachet^{L1} in 15ml water.

>20kg via tube

No

Switch to:
Esomeprazole 10 mg
sachet^{L1} in 15ml
water. If necessary,
can increase up to
20mg in 30ml water.

< 10kg oral

Switch to either:

 Omeprazole 10mg dispersible tablets^{ol} (round dose to nearest half or quarter)

Note: tablet cutter required as not scored – see <u>administration note</u>.

 If halving / quartering tablets not suitable: Omeprazole oral suspension^{L1M} SF
 Doses as per BNF-c

≥10kg – 15kg oral

• HALF Lansoprazole

Switch to either:

- 15mg dispersible tablet^{OL} (i.e. 7.5mg)

 Note: tablet cutter required as not scored see administration note.
- Omeprazole 10mg dispersible tablets^{L1}

Child weight

No

Obtain weight at the time of review and consistently at every review.

Dose as per <u>BNFc</u> or current effective dose. Choose the most cost-effective product that is suitable for the patient.

≥15 - 30kg oral

Give either:

- Lansoprazole 15mg capsule^{OL} or dispersible tablet^{OL}
- Omeprazole 20mg dispersible tablets^{L1} or capsule^{L1}.

≥ **30kg oral**Switch to either:

- Lansoprazole 30mg capsule^{OL} or dispersible tablet^{OL}
- Omeprazole 40mg dispersible tablets^{L1} or capsule^{L1}

Consider potential interactions with existing medicines—check BNF-c.

Review for ongoing need and doses may need to be adjusted according to symptoms and in line with BNFc dosing. If being used long term, the lowest effective dose should be used.



Omeprazole liquid in children and young people **Prescribing Information Sheet**

- NICE NG1¹ and ESPGHAN² recommend a 4 to 8 week trial with Proton Pump Inhibitors (PPIs) in children with symptoms of Gastro-oesophageal reflux disease (GORD). If symptoms do not resolve or reoccur, consider referral to a specialist for possible endoscopy. When symptoms persist despite adequate medical treatment, (re-) evaluate treatment compliance and differential diagnoses. Most frequently, failure of treatment will be due to one of these two causes².
- In adults, long-term PPI use has been associated with several adverse effects: increased risk of gastrointestinal and respiratory tract infection, vitamin B12 deficiency*, hypomagnesaemia*, bone fractures, acute and chronic kidney failure, and rebound hyperacidity after discontinuation. There is limited data to determine if the same adverse effects are seen in children, however until the evidence base develops further it should be assumed that children are equally at risk from these long-term adverse effects³.
 - *Consider blood monitoring if symptoms of deficiency develop.
- All patients on PPIs should be regularly reviewed, and the medicines discontinued if they are no longer deemed to be necessary. This is particularly true in the management of gastro-oesophageal reflux in neonates and infants, where PPI treatment should be reserved for cases with evidence of pathological exposure to acid reflux episodes and/or oesophagitis³.
- Clinically there is no clear evidence that one PPI is more effective than another³. The main PPIs prescribed in children are omeprazole, lansoprazole and esomeprazole. Individual patient choice will depend on several factors, including route of administration, patient age /weight, cost and palatability³. The licensing, the cost for 28 days of treatment, the formulary status and other information for the available formulations are listed below in Table 1.

Medicine	Licensing	Swallowing difficulties	Children's enteral tubes	Cost/ 28 days (Dec 21 DT)	Extra information (formulary status, bead size etc.)
Omeprazole 10mg and 20mg gastro-resistant capsule	Licensed in children greater than 1 year of age and over 10kg.	Most brands of capsules can be opened (LICENSED) and mixed with water or with a slightly acidic fluid e.g. fruit juice, applesauce. See the alternatives to using a non-licensed special document.	No	10mg - £0.98 20mg - £1.02	Green Bead size: Large (~1mm)
Omeprazole dispersible gastro-resistant tablets 10mg, 20mg and 40mg (Mezzopram is most cost- effective brand)	Licensed in children greater than 1 year of age and over 10kg.	Disperse the dispersible tablet in water, then mix this with orange / apple / pineapple juice, apple sauce, or yogurt ⁵ .	Do not use for paediatric tubes	Prices shown for Mezzopram brand: 10mg - £6.58 20mg - £9.86 40mg - £19.72	Restricted as per formulary entry. Bead size: Small (~0.2mm) Tablets are not scored but can easily be halved or quartered with a sharp knife. Neutral taste. Cordial can be added to the water to flavour it if needed.
Omeprazole 20mg/5ml oral suspension sugar free	Licensed in children greater than 1 month of age	Yes	Yes, see product SPC.	2x75ml - £402.20	No enteric coat so possibly more likely to be degraded by stomach acid. Note that 20mg/5ml is preferred regional strength
Omeprazole 10mg/5ml oral suspension	Licensed in children greater than 1 month of age	Yes	Yes, see product SPC.	2x75ml - £207.86	Amb2 No enteric coat so possibly more likely to be degraded by stomach acid. Note that 20mg/5ml is preferred regional strength
Lansoprazole 15mg and 30mg capsules	Not licensed in children	Some capsules are licensed to be opened and have their contents mixed with water, apple/tomato juice, or sprinkled on soft food (e.g. yoghurt, apple puree) to help people with swallowing difficulties ⁵ .	No	15mg - £1.00 30mg - £1.25	Green Bead size: Large ~ 1mm
Lansoprazole 15mg and 30mg oro-dispersible tablets (Zoton FasTab®)	Not licensed in children	Oro-dispersible tablets disperse in the mouth to release gastro-resistant granules. Lansoprazole is NOT absorbed sublingually. The gastro-resistant granules must be swallowed for the medicine to be effective. The FasTab® can also be administered in apple juice or orange juice ⁵ .	Do not use for paediatric tubes	15mg - £3.15 30mg - £4.63	Restricted as per formulary entry. Bead size: Small ~0.2mm Very pleasant tasting.
Esomeprazole 10mg gastro- resistant granules sachets(Nexium®)	Licensed in children greater than 1 year of age and over 10kg.	Use the granules for oral suspension. The suspension thickens after preparation ⁵ .	Yes, See product spc.	10mg - £25.19	Bead size: Small ~ 0.2mm Sachet contains beads and a thickening agent. Tastes slightly sweet and unoffensive.



From October 2020 to September 2021, there was a £402,666 spend across Nottinghamshire on omeprazole liquid for under 18s. De-prescribing or switching to more cost-effective formulations has the potential to save over £150,000 a year.

Please follow the flowchart above to review patients.

Administration note for orally administering whole, half or quarter dispersible PPI tablets:

Administration via oral syringe

- 1. Place a whole, half or quarter (as per prescription) of a dispersible tablet in barrel of oral syringe and add 5-10 mL water (non-carbonated).
- 2. Allow the tablet to disperse, shaking if necessary
- 3. Administer to the patient
- 4. Refill the syringe with approximately 2 mL of water, shake gently, and administer any remaining contents.
- 5. Take care not to crush the micro-granules as the syringe empties.
- 6. Discard the remainder of the tablet in the household waste immediately.

Administration orally via a spoon

- 1. Place a whole, half or quarter (as per prescription) of a dispersible tablet in a spoonful of non-carbonated water **DO NOT USE** milk or carbonated water.
- 2. Allow the tablet to disperse
- 3. Can be mixed with some fruit juice or apple sauce.
- 4. Administer to the patient.
- 5. Take care not to crush or chew the micro-granules.
- 6. Give half a glass of water to rinse it down.
- 7. Discard the remainder of the tablet in the household waste immediately.

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- Pediatric Gastroesophageal Reflux Clinical Practice Guidelines. ESPGHAN guidelines 2017. Available at: https://www.espghan.org/knowledge-center/publications/Gastroenterology/2017 Pediatric Gastroesophageal Reflux Clinical practice guidelines (Accessed - 9th December 2020)
- 3. Guideline for the Initiation and Monitoring of Proton Pump Inhibitors in Children, Nottingham Children's Hospital, NUH (not available on the NUH intranet but can be accessed upon request)
- 4. Pharmaceutical Press. BNF for Children 2019-20 (Accessed online in August 2021 via https://bnfc.nice.org.uk/about/)
- 5. NEWT guidelines (Accessed Online in August 2021 via NEWT Guidelines)
- 6. PrescQIPP Bulletin 267: PPIs Long term safety and gastroprotection: Proton Pump Inhibitor (PPI): Deprescribing algorithm (adults) (Accessed online in August 2021 via <u>Bulletins (prescqipp.info)</u>).