

Supplement: Omeprazole / Lansoprazole / Ranitidine in Infants

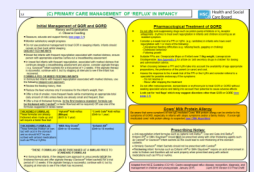
Choosing a suitable formulation of omeprazole / lansoprazole / ranitidine for infants can be problematic. Clinical practice does not always reflect the licensed products available. The purpose of this newsletter supplement is to assist clinicians and pharmacists in selection and administration of suitable products.

Last year, unlicensed 'specials' of omeprazole, lansoprazole and ranitidine cost the NHS in Northern Ireland over £1,000,000.

While a suspension may be needed in some patients, it is often not the best option

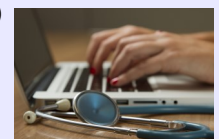
Guidance on managing reflux in infants

If clinically indicated, a 4 week time-limited trial of a H₂-receptor antagonist or a proton pump inhibitor (PPI) may be considered.¹ Please refer to Northern Ireland Infant feeding guideline on the [NI Formulary website](#) for full details on managing reflux.



Choice of PPI — lansoprazole or omeprazole?

Royal Belfast Hospital for Sick Children (RBHSC) and the Royal Jubilee Maternity Service (RJMS) neonatal unit are moving to use lansoprazole orodispersible tablets as their preferred option. This is preferred over omeprazole suspension for a number of reasons, including bioavailability issues with omeprazole suspension, problems with enteral feeding tube blockage with omeprazole, and cost.²



'Off-label' use or unlicensed 'special'?

The General Medical Council advises that licensed medicines and indications should be used where possible. If this is not an option, consider using a licensed medicine in an unlicensed manner ('off-label' use). 'Specials' are unlicensed medicines and are not required to meet the same standards as licensed preparations. Prescribers assume greater liability when using them and they are considerably more expensive than licensed medicines.³ Practice-generated scripts for omeprazole or lansoprazole suspension will result in an unlicensed product being dispensed to the patient. Refer to ['specials' supplement](#) on NI Formulary website for further information on 'specials'.



The role of the community pharmacist

If omeprazole or lansoprazole suspension is prescribed, it has to be ordered as an unlicensed 'special', and costs can vary greatly. Community pharmacists are asked to inform the prescriber of the cost of omeprazole or lansoprazole suspension compared to orodispersible tablets before placing an order with a special order company. If the suspension continues to be prescribed, please consider checking alternative suppliers for cost-effective prices.



A need for review

As with any medicine, it is important to review the continued need for H₂-receptor antagonist or PPI use. Risks associated with long-term use of PPIs have been reported. See Medicines Management Newsletter article August 2015 on [NI Formulary website](#).

If there is need for continued use, i.e. the child continues to be symptomatic, ensure that the dose is still suitable for the child's weight, i.e. dose escalation of the H₂-receptor antagonist or PPI may be required as the child gains weight.



Healthcare professionals should explore all alternatives before deciding to prescribe a 'special'

OMEPRAZOLE

Paediatric license: omeprazole is licensed for use in children from 1 year and > 10kg for the treatment of reflux oesophagitis, symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease.^{4,5} In clinical practice, omeprazole is also used off license in children under 1 year.²

Preparations: 10mg and 20mg tablets (MUPS[®]), 10mg and 20mg capsules, 10mg/5mL suspension (manufactured extemporaneously or ordered as a 'special').

Omeprazole Dosage⁶

Age/weight	Dose	It is important that calculated doses are then considered in practical terms, in relation to available products, i.e. round to the nearest 5mg. In practice, children with a weight of ≥ 3.4kg may be given a dose of 10mg daily. ² A 5mg dose is usually only prescribed in the hospital setting for babies of low weight. ³
Neonate	700 micrograms/kg once daily (max. 2.8mg/kg)	
1mth to 2yr	700 micrograms/kg once daily (up to 3mg/kg; max.20mg)	
10 to 20kg	10mg once daily (max.20mg)	
Child >20kg	20mg once daily (max.40mg)	

Omeprazole Unlicensed 'Specials'

- There is only limited evidence of efficacy for the omeprazole suspension. Orodispersible tablets should be used where possible.⁷
- The sodium bicarbonate in the suspension gives it an unpleasant taste and a high sodium content.
- The suspension is usually reserved for children with feeding tubes under 12Fr in size.
- Omeprazole suspension can be ordered as an unlicensed preparation from special order companies. They are often formulated in the same way as the extemporaneous formulation, i.e. using omeprazole capsules in sodium bicarbonate.
- The price of omeprazole suspension can vary greatly between special order companies: invoices to BSO range from £23 to £1664 for omeprazole 10mg/5ml oral suspension.
- **Please ensure a cost-effective product is ordered.**

An extemporaneous formulation can be made up in pharmacies. However, if a suspension is required, it is preferred that this is ordered from a company with a 'specials' manufacturing licence.



Omeprazole 10mg/5mL suspension Extemporaneous Formulation⁸

Ingredients:

Omeprazole capsules 20mg x 28
Sodium bicarbonate 8.4% x 280mL

Method: Open the omeprazole capsules and place contents in a mortar. Crush the granules and mix with a little sodium bicarbonate 8.4%. Make up to volume with the remainder of the sodium bicarbonate solution. Transfer to an amber bottle with an adaptor, label appropriately, and supply with an oral syringe.

COSHH requirements: wear gloves

Expiry: 28 days in fridge (2 to 8°C)

Oral administration of Losec MUPS[®] tablets

Children <1year who are not spoon fed:

- Use an oral syringe to administer the tablet.
- If a dose of 5mg is required, halve the tablet (using a tablet cutter) before dispersing.
- Place the tablet (or half of a tablet) in the barrel of an oral syringe.
- Replace the plunger and draw up 10mL of water. The resulting dispersion will contain enteric coated pellets.
- Give the 10mL dispersion to the infant.

If a 10mL oral syringe is not available, a medicine cup or 5mL oral syringe may be used to disperse the tablet in water. However, it is important to ensure that ALL of the pellets are drawn up into the oral syringe and administered.

Note: pellets tend to settle to the bottom in oral syringes / medicine cups and there is a risk that the child may not receive the full dose: ensure that all of the pellets are drawn up and administered

Aliquots are not suitable for administering doses under 10mg, i.e. do not try to dissolve a 10mg tablet in 10mL of water and assume 5mL will equal 5mg, as the pellets do not dissolve.⁷

Children who are spoon fed:

Disperse the tablet (or half tablet, depending on dose) in a spoonful of non-carbonated water. If so wished, the dispersion may then be mixed with fruit juice or apple sauce. Always stir just before drinking and rinse down with half a glass of water. Do not use milk or carbonated water. Do not chew the enteric-coated pellets.⁵

Enteral Feeding administration

Omeprazole capsules and MUPS[®] tablets are unlicensed via enteral feeding tubes but, in practice, MUPS[®] tablets will flush through tubes ≥ 12Fr. Omeprazole suspension or lansoprazole orodispersible tablets may be considered in finer bore tubes.^{7,9,10}

LANSOPRAZOLE

Paediatric license: Lansoprazole is not licensed in children due to limited clinical data.¹¹ However there is increasing clinical experience and the Children's BNF provides information on use of lansoprazole in infants.

Preparations: 15mg and 30mg Fastabs[®], 15mg and 30mg capsules, oral suspension of various strengths (manufactured extemporaneously or ordered as a 'special').

Lansoprazole Dosage⁷

Body weight	Dose	Preparation
For infants under 2.5kg, there is less clinical experience with lansoprazole, therefore use omeprazole		
2.5 to 5kg	3.75mg once daily	Quarter a 15mg tablet
5 to 10kg	7.5mg once daily	Half a 15mg tablet
10 to 30kg	15mg once daily	One 15mg tablet
> 30kg	30mg once daily	One 30mg tablet

Lansoprazole Unlicensed 'Specials'

- There is limited evidence of efficacy for the lansoprazole suspension. Therefore, orodispersible tablets should be used where possible.⁷
- The sodium bicarbonate in the suspension gives it an unpleasant taste and a high sodium content.
- The suspension is usually reserved for children with feeding tubes under 12Fr in size.
- The price of lansoprazole suspension can vary greatly between special order companies. **Please ensure a cost-effective product is ordered.**



Lansoprazole oral suspension Extemporaneous Formulation

An oral suspension has been made with sodium bicarbonate, but is not as stable as omeprazole in sodium bicarbonate.

Oral administration of orodispersible tablets[®]

Children <1year who are not spoon fed:

- Use an oral syringe to administer the tablet.
- If a dose of 7.5mg is required, halve the tablet; if a 3.75mg dose is required, quarter the tablet (using a tablet cutter) before dispersing.
- Place the tablet (or half of a tablet) in the barrel of an oral syringe.
- Replace the plunger and draw up 10mL water. The dispersion will contain enteric coated pellets.
- Give the 10mL dispersion to the infant.

If a 10mL oral syringe is not available, a medicine cup or 5mL oral syringe may be used to disperse the tablet in water. However, it is important to ensure that ALL of the pellets are drawn up into the oral syringe and administered.

Note: pellets tend to settle to the bottom in oral syringes / medicine cups and there is a risk that the child may not receive the full dose: ensure that all of the pellets are drawn up and administered

Aliquots are not suitable for administering doses under 10mg.⁷

Children who are spoon fed:

Disperse the tablet (or fraction of) in a spoonful of non-carbonated water. FasTabs[®] may also be given with apple juice or orange juice.¹⁰ Always stir just before drinking and rinse down with half a glass of water.

Enteral Feeding administration

FasTabs[®] are licensed for administration via nasogastric tube and will fit through feeding tubes of size ≥8Fr.^{9,11}

RANITIDINE

Paediatric license: Ranitidine is not licensed in children below 3 years of age. However there is experience with the use of ranitidine in infants, and the Children's BNF provides information on doses of ranitidine in infants.⁶

Preparations: 150mg/10mL oral solution, 75mg, 150mg and 300mg tablets, 150mg and 300mg effervescent tablets, oral suspension of various strengths (manufactured extemporaneously or ordered as a 'special').

Ranitidine Dosage⁶

Age	Dose
Neonate	2mg/kg three times daily
1 to 6mths	1mg/kg three times daily
6mths to 3yrs	2 to 4mg/kg twice daily

Oral administration

The **licensed** 150mg/10mL liquid should be prescribed with a 1mL syringe to administer small doses to children, e.g. a dose of 4.3mg equates to 0.29mL.² See page 4.

Note: expiry of ranitidine liquid once opened.

Enteral Feeding administration

Although not licensed for enteral administration, the liquid preparation can be used for gastric administration (but note sorbitol content).⁹

Ranitidine Unlicensed 'Specials'

- The licensed 150mg/10mL liquid should be used instead of diluting the licensed product or ordering unlicensed 'specials'.
- A 1mL oral syringe should be dispensed with the licensed liquid.
- Rosemont and Zantac® liquids are sucrose-free but contain 8%w/v alcohol.^{6,7} However, this generally is considered insignificant when given in such small quantities to infants.
- The licensed 150mg/10mL liquid costs £6.45 for 300mL; the cost of an unlicensed liquid can be up to £474.



Oral syringes

- Community pharmacies can order 1mL, 3mL and 5mL oral syringes from local pharmaceutical wholesalers.
- 1mL and 3mL syringes are available in small packs or single packs to avoid bulk buying and cost less than £1 each.
- Only the 5mL size oral syringe is currently on NI Drug Tariff.¹³
- 10mL oral syringes are available from local medical suppliers.

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