Due to differences between product licences and clinical practice, product choice of anti-secretory drugs for infants can be problematic. The purpose of this 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 £800,000. Such 'specials' cost on average £220 per bottle. While a suspension may be needed in some patients, it is not always the best option.

**HSCB Guidance on managing reflux in infants**

If clinically indicated, a 4 week time-limited trial of a H$_2$-receptor antagonist or a proton pump inhibitor (PPI) may be considered. Please refer to HSCB Infant feeding guideline for full details on managing reflux: [http://niformulary.hscni.net/Formulary/Adult/PDF/PrimaryCareInfant_Feeding_GuidelinesWeb.pdf](http://niformulary.hscni.net/Formulary/Adult/PDF/PrimaryCareInfant_Feeding_GuidelinesWeb.pdf)

‘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 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. Practice-generated scripts for omeprazole or lansoprazole suspension will result in an unlicensed product being dispensed to the patient.

**Choice of PPI — lansoprazole or omeprazole?**

Royal Belfast Hospital for Sick Children (RBHSC), are moving away from using omeprazole as the first choice PPI in preference to lansoprazole in infants ≥ 7.5kg. This is due to difficulties administering low doses in infants, bioavailability issues with omeprazole suspension and problems with enteral feeding tube blockage. Therefore you may see more requests from secondary care to prescribe lansoprazole orodispersible. Other local Trusts are currently still using omeprazole as the first line PPI of choice.

**Need for review**

As with any medicine, it is important to review the continued need for H$_2$-receptor antagonist or PPI use. Risks associated with long-term use of PPIs have been reported. See Medicines Management Newsletter article August 2015: [http://niformulary.hscni.net/PrescribingNewsletters/PDF/NIMM_2015/NIMM_NewsletterVol6Issue8Aug15.pdf](http://niformulary.hscni.net/PrescribingNewsletters/PDF/NIMM_2015/NIMM_NewsletterVol6Issue8Aug15.pdf)

If there is need for continued use, i.e. the child continues to be symptomatic, dose escalation of the H$_2$-receptor antagonist or PPI may be required, as the child gains weight.
**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. In clinical practice, omeprazole is also used off license in children under 1 year.

**Preparations:** 10mg and 20mg tablets (MUPS®), 10mg and 20mg capsules, 2mg/mL suspension (manufactured extemporaneously or ordered as a special). MUPS® tablets should be used where possible. There is only limited evidence of efficacy for the omeprazole suspension. Furthermore 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 Dosage

<table>
<thead>
<tr>
<th>Age/weight</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonate</td>
<td>700 micrograms/kg daily (max. 2.8mg/kg)</td>
</tr>
<tr>
<td>1mth to 2yr</td>
<td>700 micrograms/kg daily (up to 3mg/kg; max. 20mg)</td>
</tr>
<tr>
<td>10 to 20kg</td>
<td>10mg daily (max. 20mg)</td>
</tr>
<tr>
<td>Child &gt;20kg</td>
<td>20mg daily (max. 40mg)</td>
</tr>
</tbody>
</table>

It is important that calculated doses are practical in terms of available products. In practice, children with a weight of ≥ 3.4kg are given a dose of 10mg daily. A 5mg dose is usually only prescribed in the hospital setting for babies of low weight.

### Oral administration:

**Administration of MUPS® tablets to children <1year not spoon fed**

Follow the same procedure as Zoton FasTab®. See administration box. If a dose of 5mg is required, halve the tablet (using a tablet cutter) before dispersing: aliquots are not suitable for administering doses under 10mg.

**Administration of MUPS® tablets to children who are spoon fed**

Break the tablet and disperse it 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.

### Enteral Feeding administration:

Omeprazole capsules and MUPS® tablets are unlicensed via enteral feeding tubes but, in practice, MUPS® tablets will flush though tubes ≥ 12Fr. Omeprazole suspension or lansoprazole orodispersible tablets may be considered in finer bore tubes.

### Omeprazole 2mg/mL suspension

**Extemporaneous Formulation**

**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 8C)

### Unlicensed Specials

Omeprazole suspension is available as an unlicensed preparation from several specials companies. These can be costly and often are formulated in the same way as the extemporaneous formulation, i.e. using omeprazole capsules in sodium bicarbonate. See ‘Special-order Manufacturers’ in BNF for a list of NHS hospital manufacturers.
LANSOPRAZOLE

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

Preparations: 15mg and 30mg Fastabs®

<table>
<thead>
<tr>
<th>Body weight</th>
<th>Dose</th>
<th>Preparation</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5kg</td>
<td>7.5mg once daily</td>
<td>Half a 15mg tablet</td>
</tr>
<tr>
<td>7.5kg to 15kg</td>
<td>7.5mg once daily (use clinical judgement closer to 15kg)</td>
<td>Half to one 15mg tablet</td>
</tr>
<tr>
<td>16kg to 30kg</td>
<td>15mg once daily</td>
<td>One 15mg tablet</td>
</tr>
<tr>
<td>≥ 30kg</td>
<td>15 to 30mg once daily</td>
<td>One 15mg or one 30mg tablet</td>
</tr>
</tbody>
</table>

Oral administration

Administration of FasTabs® to children <1 year who are not spoon fed

See administration box. If a dose of 7.5mg is required, halve the tablet (using a tablet cutter) before dispersing: aliquots are not suitable for administering doses under 15mg.

Administration of FasTabs® to children who are spoon fed

Break the tablet and disperse it in a spoonful of non-carbonated water. The FasTabs® may also be administered with apple juice or orange juice. 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.

RANITIDINE

If ranitidine is indicated, the licensed 75mg/5mL liquid should be prescribed with a 1mL syringe to administer small doses to children, e.g. 0.29mL for 4.3mg. See children’s BNF for full dosage instructions.

This approach should be used instead of diluting the licensed product or ordering unlicensed specials. Rosemont and Zantac® liquids are sucrose-free but contain 8%w/v alcohol. However, this generally is considered insignificant when given in such small quantities to infants.
References
3. Personal Communication, RBHSC.
7. EMC. Zoton FasTab SPC,06/07/2012. http://www.medicines.org.uk
13. NICE. NICE NG1 Gastro-oesophageal reflux disease in children and young people: diagnosis and management. 2015

This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

Belfast Office: 028 9536 3926
South Eastern Office: 028 9147 5133
Southern Office: 028 9536 2104
Northern Office: 028 9536 2845
Western Office: 028 9536 1008

Every effort has been made to ensure that the information included in this newsletter is correct at the time of publication. This newsletter is not to be used for commercial purposes.