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SAFER USE OF HIGH RISK MEDICINES

Waitemata District Health Board
Best Care for Everyone

OMEPRAZOLE FOR CHILDREN – SAFE PRESCRIBING – THE INS AND OUTS

- EXPLAIN TO CAREGIVERS THAT MANY INFANTS WITH REFLUX/GORD IMPROVE WITHOUT MEDICATION
- REASSURE CAREGIVERS THAT IRRITABILITY, CRYING AND FUSSING ARE COMMON – OMEPRAZOLE DOES NOT CHANGE THESE BEHAVIOURS
- CONSIDER THE POTENTIAL INCREASED RISK OF INFECTIONS BEFORE PRESCRIBING
- USE MEDICATION FOR A LIMITED TIME

Uncomplicated infant reflux is common, and often due to large quantities of milk being ingested relative to the size of the infant's stomach. Almost all preterm infants show some degree of reflux which usually improves as the infant grows and the digestive system matures.

GORD (Gastro-Oesophageal Reflux Disease) has been defined as 'when the reflux of gastric contents causes troublesome symptoms and/or complications'.

EXPLAIN TO CAREGIVERS THAT MANY INFANTS WITH REFLUX/GORD IMPROVE WITHOUT MEDICATION

All that is usually required for children under 12 months of age who are thriving and have uncomplicated reflux, is reassurance and conservative management such as adequate burping, thickened feeds, and avoiding overfeeding.

Omeprazole reduces gastric acidity, not the frequency of reflux events; it is not considered effective for treating symptoms of infant reflux. Reassure caregivers that most cases will spontaneously resolve, usually when the child begins to adopt an upright posture or consume solids. In New Zealand, *proton pump inhibitors (PPIs) are not approved for use in infants under 12 months of age.*

REASSURE CAREGIVERS THAT IRRITABILITY, CRYING AND FUSSING ARE COMMON – OMEPRAZOLE DOES NOT CHANGE THESE BEHAVIOURS

Omeprazole does not suppress irritability, crying or fussing compared to placebo. Reassure caregivers that crying patterns vary with age; crying frequency usually peaks between 6 weeks and 3 months, and 3 hours per day can be considered 'normal'.

The benefits of simple, conservative treatment such as adequate burping, thickened feeds, and avoidance of passive smoking should be explored before pharmacological measures are considered.

CONSIDER THE POTENTIAL INCREASED RISK OF INFECTIONS BEFORE PRESCRIBING

Emerging evidence suggests that omeprazole may increase the risk of community acquired pneumonia (CAP) and gastroenteritis. This may be due to the role of gastric acid as a means of limiting the survival of microorganisms and regulation of gastrointestinal microflora.

Omeprazole should only be considered for severe infantile reflux oesophagitis, or if there are related complications such as failure to thrive. The decision to prescribe should be in consultation with a paediatrician or paediatric gastroenterologist.

USE MEDICATION FOR A LIMITED TIME

If the decision is made to prescribe a PPI, reassess symptoms after 2 to 4 weeks. If there is no benefit, consider other options with a specialist. Side effects of omeprazole include nausea and vomiting, constipation, diarrhoea and abdominal pain. If symptoms worsen with treatment refer to a paediatric gastroenterologist.

Please inform caregivers that omeprazole suspension will need to be prepared at a community pharmacy. The recommended formula is for 2mg/mL and has a 15 day expiry when kept in the fridge.

Information for parents and carers is available via the New Zealand Formulary for Children www.nzfchildren.org.nz/nzf/resource/MFC/MfC_Omeprazole_for_GORD.pdf

When to Refer

Refer to a paediatrician if the infant has excessive reflux **and**:

- Conservative treatment has failed (burping, small volume feeds, smoke-free environment, thickened feeds) or
- Extreme parental anxiety or
- Diagnostic uncertainty or
- Presence or suspicion of complications:
  - Failure to thrive
  - Oesophagitis
  - Respiratory complications
  - Neurobehavioural symptoms

➥ continued

OMEPRAZOLE

OMEPRAZOLE COMPOUNDING FOR PHARMACISTS

Omeprazole is unstable in acidic conditions; a suspension in sodium bicarbonate solution can be prepared as below.

Note: There are enteric coated pellets inside the capsules. The capsules should not be dissolved in milk or water.

Formula

Omeprazole suspension 2mg/mL

Omeprazole powder	100mg
(**Or** omeprazole capsules	20mg x 5)
Sodium bicarbonate powder	4.2g
Water	50ml

Method

- Weigh sodium bicarbonate powder and grind in mortar and pestle to remove lumps
- Add powder to approximately 40ml water and stir until dissolved
- Put omeprazole powder into mortar (OR If using capsules, empty capsule contents into mortar and use pestle to crush the granules into a fine powder)
- Add a small volume of sodium bicarbonate solution, triturate to make a paste
- Transfer paste to measure and make up to final volume with sodium bicarbonate solution

Expiry: 15 days under refrigeration

Storage: Omeprazole is light sensitive. Store in amber plastic or glass containers. A colour change (to orange or black) may occur on exposure to light.

SHAKE THE BOTTLE because omeprazole is incompletely dissolved and partly in suspension.

Alternatively, if exactly 10mg or 20mg is prescribed, the capsule can be carefully opened and the granules mixed with a small amount of soft food (yoghurt/fruit puree). It is important the total amount is given straight away. The granules must not be crushed or chewed.

Capsule contents must not be directly placed on the child's tongue.

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KEY REFERENCES

1. Reith D, Leathart C, Alderton A. Irritable infants, reflux and GORD. Best Practice Journal 2011; 40: 30-37 www.bpac.org.nz/BPJ/2011/november/infant-reflux.aspx (Accessed 20-05-16)
2. Starship Hospital Clinical Guidelines. Gastro-oesophageal Reflux 2012. www.adhb.govt.nz/starshipclinicalguidelines/_Documents/Gastro-Oesophageal%20Reflux.pdf (Accessed 20-05-16)
3. New Zealand Formulary for Children. Gastro-oesophageal reflux disease. www.nzfchildren.org.nz/nzf_655 (Accessed 04-07-16)
4. New Zealand Formulary. Omeprazole suspension. www.nzf.org.nz/nzf_9669.html (Accessed 04-07-16)

CLICK HERE FOR FURTHER INFORMATION ON OMEPRAZOLE AND A FULL REFERENCE LIST

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