OMEPRAZOLE

Indication	• Treatment of symptomatic gastro-oesophageal reflux[1] • Relapse prevention in reflux oesophagitis[2] • Treatment of gastric haemorrhage • Oesophageal protection following trachea-oesophageal atresia repair[3]

ORAL

Presentation	• Oral solution: 2 mg in 1 mL
Dosage	• Initial dose: 1 mg/kg once daily[4] (*or* divide into equal doses twice daily) • After 7–14 days of treatment, review clinical response[1] o If required, increase by 0.5 mg/kg per day o Maximum dose of 2.5 mg/kg once daily[1]
Preparation	• No additional preparation required • Shake bottle well before use
Administration	• Draw up prescribed dose and give immediately • Oral/OGT/NGT before feeds

INTRAVENOUS

Presentation	• Vial: 40 mg powder
Dosage[5,6]	• 1 mg/kg every 12 hours o If bleeding is acute, consider more frequent dosing interval • Maximum dose 2 mg/kg/day
Preparation	• Add 5 mL of 0.9% sodium chloride to 40 mg vial o *Concentration now equal to 8 mg/mL* • From the 8 mg/mL solution draw up 8 mg (1 mL) and make up to 20 mL total volume with 0.9% sodium chloride o *Concentration now equal to 0.4 mg/mL*
Administration	• Prime the infusion line and reduce total syringe volume to the prescribed dose • IV infusion via syringe driver pump over 20–30 minutes[7] • On completion, disconnect syringe and infusion line • Flush access port at same rate as infusion

Special considerations	• Prolonged use (more than 3 months) may result in hypomagnesaemia[1] • If oral solution unavailable or if preferred at discharge, may use 10 mg tablet[8] o Use mg/kg dosing and round to nearest 5 mg[8] o Tablet disperses into enteric coated granules that settle quickly o Seek pharmacist advice for preparation • Cautions (especially in absence of diagnosed GORD) o Case control studies suggest increased risk of infection including NEC, pneumonia, URTI, sepsis, UTI and *Clostridium difficile* infections with PPI use[9] o May be associated with development of allergic immune system responses (e.g. food allergies and asthma)[10]
Monitoring	• If duration of use greater than 3 month, monitor serum magnesium levels[4] • If receiving phenytoin, reduction in phenytoin dose may be necessary
Compatibility	• Fluids o 5% glucose[7], 0.9% sodium chloride[7] • Drugs (via Y-site, or in syringe) o No information[7]
Incompatibility	• Fluids o No information[7] • Drugs o Midazolam[7], vancomycin[7]

Interactions	• Oral: may increase or decrease absorption of a drug that is influenced by gastric acidity (e.g. digoxin), as omeprazole decreases acidity[11] • Phenytoin: reduces plasma clearance of intravenous phenytoin by 15–20% and increases the elimination half-life by 27%[11] • Voriconazole, fluconazole: increases plasma concentration of omeprazole[1] • Levothyroxine: can decrease absorption of levothyroxine due to effect on gastric acidity. Separate administration by 4 hours[4]
Stability	• Oral solution o Store in fridge at 2–8 °C o Discard according to expiry date on bottle • Vial o Store below 25 °C[7]. Protect from light[7]
Side effects	• Blood pathology (uncommon): leucopaenia[1], thrombocytopenia[1] hyponatraemia, increased liver enzymes[1] • Digestive: vomiting[1], diarrhoea[1], constipation[1], may increase risk of GIT infections[12] o Vomitus may be dark purple (if exposed to acid in the stomach, medicine changes colour). Not harmful but may indicate reduced bioavailability and efficacy[13] • Nervous: rash[1], agitation[1], drowsiness[1]
Actions	• Reversibly reduces gastric acid secretion by specifically inhibiting the gastric enzyme H+, K+- ATPase proton pump in the parietal cell[1,11] • Is dose dependent and effectively inhibits both basal acid secretions and stimulated acid secretion irrespective of the stimulus to acid production[11]
Abbreviations	GORD: gastro-oesophageal reflux disease) IV: intravenous, NEC: necrotising enterocolitis, NGT: nasogastric tube, OGT: orogastric tube, PPI: protein pump inhibitor, URTI: upper respiratory tract infection, UTI: urinary tract infection
Keywords	neonatal medicine, neonatal monograph, reflux, oesophagitis, gastric haemorrhage, omeprazole, losec, protein pump inhibitor, gastro-oesophageal reflux disease, GORD

The Queensland Clinical Guideline *Neonatal Medicines* is integral to and should be read in conjunction with this monograph. Refer to the disclaimer. Destroy all printed copies of this monograph after use.

References

1. British National Formulary for Children (BNFC) online. Omeprazole. [Internet]: Royal Pharmaceutical Society; February 2022 [cited 2023 January 17]. Available from: https://www.medicinescomplete.com.
2. Therapeutic Goods Administration (TGA). Omeprazole product information. [Internet]. Canberra: Australian Government; November 2019 [cited 2023 January 30]. Available from: https://www.tga.gov.au.
3. Krishnan U, Mousa H, Dall'Oglio L, Homaira N, Rosen R, Faure C, et al. ESPGHAN-NASPGHAN Guidelines for the Evaluation and Treatment of Gastrointestinal and Nutritional Complications in Children With Esophageal Atresia-Tracheoesophageal Fistula. J Pediatr Gastroenterol Nutr 2016;63(5):550-70.
4. IBM Micromedex®Neofax®. Omperazole. In: IBM Micromedex® NeoFax®/Pediatrics (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. 2023 [cited 2023 March 31]. Available from: http://neofax.micromedexsolutions.com/neofax.
5. Solana MJ, López-Herce J, Sánchez A, Sánchez C, Urbano J, López D, et al. 0.5 mg/kg versus 1 mg/kg of intravenous omeprazole for the prophylaxis of gastrointestinal bleeding in critically ill children: a randomized study. J Pediatr 2013;162(4):776-82.e1.
6. Omari TI, Haslam RR, Lundborg P, Davidson GP. Effect of omeprazole on acid gastroesophageal reflux and gastric acidity in preterm infants with pathological acid reflux. J Pediatr Gastroenterol Nutr 2007;44(1):41-4.
7. Australian Injectable Drugs Handbook. Nicolette Burridge, Keli Symons, editors. Omeprazole. 8th ed. [Internet]. New South Wales: Society of Hospital Pharmacists of Australia (SHPA); November 2022 [cited 2023 January 17]. Available from: https://aidh.hcn.com.au.
8. Queensland Health. List of Approved Medications (LAM). [Internet]. 2023 [cited 2023 April 20]. Available from: https://www.health.qld.gov.au.
9. Rosen R, Vandenplas Y, Singendonk M, Cabana M, DiLorenzo C, Gottrand F, et al. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatr Gastroenterol Nutr 2018;66(3):516-54.
10. Safe M, Chan WH, Leach ST, Sutton L, Lui K, Krishnan U. Widespread use of gastric acid inhibitors in infants: Are they needed? Are they safe? World J Gastrointest Pharmacol Ther 2016;7(4):531-9.
11. MIMS Online. Omeprazole. [Internet]: MIMS Australia; January 2020 [cited 2023 January 30]. Available from: https://www.mimsonline.com.au.
12. Guillet R, Stoll BJ, Cotten CM, Gantz M, McDonald S, Poole WK, et al. Association of H2-blocker therapy and higher incidence of necrotizing enterocolitis in very low birth weight infants. Pediatrics 2006;117(2):e137-42.
13. van Hunsel F, de Jong L, de Vries T. (Es)omeprazole and Discoloration of Regurgitated Gastric Contents in Infants: Worrying for Care-Takers and a Sign of a Reduced Bioavailability. J Pediatr Pharmacol Ther 2016;21(3):260-2.

Document history

ID number	Effective	Review	Summary of updates
NMedQ23.105-V1-R28	13/06/2023	13/06/2028	Endorsed by Queensland Neonatal Services Group (QNSAG)

QR code