### Alert
Short- and long-term safety data in infants are limited. There have been several safety concerns with long-term usage in adults. The bioavailability of the in-house pharmacy suspension made from the contents of the capsule may be less (up to 50% less) than that of the capsule itself. Dose may need to be adjusted if no clinical response.

### Indication
- Treatment of gastroesophageal reflux disease (GORD).
- Prophylaxis in congenital tracheoesophageal fistula and oesophageal atresia (role unclear).

### Action
Omeprazole is a proton pump inhibitor (PPI).

### Drug Type
Proton Pump Inhibitor.

### Trade Name
- APO-Omeprazole Capsules (Apotex) 20 mg
- Omeprazole Sandoz IV Powder for injection (Sandoz) 40 mg.

### Presentation
- 20 mg/capsule; 10 mg tablets; 20 mg tablets.
- Oral suspension of 2 mg/mL prepared in pharmacy.
- Omeprazole Sandoz IV Powder for injection 40 mg.

### Dosage / Interval
- **PO:** 0.5–1.5 mg/kg/dose daily
- **IV:** 0.5 mg/kg/dose daily

### Maximum daily dose
1.5 mg/kg/dose

### Route
PO, IV

### Preparation/Dilution
- **PO:** In-house pharmacy can prepare a 2 mg/mL suspension using these capsules as follows: Disperse 100 mg omeprazole in 50 mL of 8.4% sodium bicarbonate solution. 1 mL of omeprazole suspension contains 2 mg omeprazole, 1 mmol sodium and 1 mmol bicarbonate.
- **IV:** Reconstitute the vial with 5 mL from a 100 mL bag of sodium chloride 0.9% or glucose 5%. Add the reconstituted solution back into the 100 mL bag to obtain 0.4 mg/mL.

### Administration
- **PO:** Administer prior to meals.
- **IV:** Infuse over 30 minutes.

### Monitoring
Serum magnesium, in patients on prolonged therapy or who use diuretics that may cause hypomagnesaemia (e.g. diuretics) concomitantly.
- Serum vitamin B₁₂ — every 1 to 2 years in patients on prolonged therapy.

### Contraindications
Hypersensitivity to any component of the product.

### Precautions
- Concurrent use of ketoconazole may result in decreased ketoconazole exposure.
- Concurrent use of fluconazole may result in increased plasma concentrations of omeprazole.
- Concurrent use of iron may result in reduced non-heme iron bioavailability.

### Drug Interactions
- Common
- Dermatologic: Rash
- Gastrointestinal: Increased risk of *Clostridium difficile*-associated diarrhea (CDAD), Abdominal pain, constipation, diarrhea, flatulence, vomiting
- Respiratory: Upper respiratory infection (adults)
- Other: Fever (1 to less than 2 years, 33%)

### Adverse Reactions
- Serious
- Dermatologic: Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis
- Endocrine: Hypomagnesaemia
- Gastrointestinal: Atrophic gastritis, *Clostridium difficile* diarrhea, pancreatitis
- Haematological: Haemolytic anaemia
- Hepatic: Hepatic encephalopathy, hepatic necrosis, liver failure
- Immunological: Anaphylaxis
- Musculoskeletal: Fracture of bone, hip fracture, rhabdomyolysis
- Renal: Acute interstitial nephritis
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| Incompatibility | Oral: No information.  
IV: No information. |
| Stability     | Prepared suspension is stable for 30 days. Refrigerate. Protect from light. Shake the bottle well before administration.  
IV reconstituted solution and diluted solution: Stable for 6 hours below 25°C. Protect from light. |
| Storage       | Oral suspension: Refrigerate (2–8°C) the prepared suspension.  
Injection: Store below 25°C. Protect from light. |
| Special Comments |  |
| Evidence summary | As per NMF Consensus Group. Refer to reference manual or electronic version. |
| References    | As per NMF Consensus Group. Refer to reference manual or electronic version. |

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Author: Neonatal Medicines Formulary Consensus Group

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