### 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:** Add 10 mL of sodium chloride 0.9% to 40 mg powder for reconstitution to make a concentration of 4 mg/mL. Draw up 1 mL (4 mg) and add 9 mL of sodium chloride 0.9% to make a final volume of 10 mL with a concentration of 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 digoxin or drugs that may cause hypomagnesaemia (e.g. diuretics) concomitantly.\(^{20-21}\)
- Serum vitamin B₁₂ — every 1 to 2 years in patients on prolonged therapy.\(^{20-21}\)

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

### Precautions

### Drug Interactions
- 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.

### Adverse Reactions
**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% )

**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
| Compatibility | Musculoskeletal: Fracture of bone, hip fracture, rhabdomyolysis  
Renal: Acute interstitial nephritis |
|---------------|---------------------------------------------------------------|
| 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 | 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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