### Alert
Short and long-term safety data in infants are limited.

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

### Action
Proton pump inhibitor (PPI). Bind to the hydrogen/potassium ATPase enzyme system (proton pump), inhibiting both stimulated and basal acid secretion.

### Drug Type
Proton Pump Inhibitor.

### Trade Name
- Oral tablet: Multiple brands available.
- Oral capsule: Multiple brands available.
- IV: Omeprazole Sandoz Powder for Injection.

### Presentation
- Oral: Available in 10mg and 20 mg. Available in capsules or enteric coated tablets.
- Oral suspension of 2 mg/mL, 5mg/mL or other strengths may be prepared in pharmacy.
- IV: 40mg/vial of Omeprazole in dry powder form.

### Dose
**PO:** 1-2.5 mg/kg/day in 1 to 2 divided doses (1,2)
**IV:** 0.5 mg/kg/dose 12-24 hourly (3,4,5,6)

### Dose adjustment
- Therapeutic hypothermia – No information.
- ECMO – No information.
- Renal impairment – No dose adjustment is required.
- Hepatic impairment – Dose reduction is recommended. However, no specific information available.

### Maximum daily dose
2.5 mg/kg/day (1)

### Total cumulative dose

### Route
PO, IV

### Preparation
**PO:** 2 mg/mL oral suspension (prepared by hospital pharmacy).
**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. Shake the bottle well before administration.
**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.
Serum vitamin B12 — every 1 to 2 years in patients on prolonged therapy.

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

### Precautions
Short- and long-term safety data in infants are limited. There have been safety concerns with long term usage in adults. Current FDA’s maximum recommended duration of therapy of PPIs is up to 8 weeks.

### Drug Interactions
Concurrent use of fluconazole may result in increased plasma concentrations of omeprazole.
Concurrent use of iron may result in reduced non-heme iron bioavailability.
Omeprazole is mainly metabolised via hepatic cytochrome P450 system (CYP2C19) and may be expected to interact with the metabolism of other drugs metabolised by this enzyme.
Omeprazole may reduce phenytoin clearance – monitor phenytoin levels.
Omeprazole produces a profound and sustained inhibition of gastric acid secretion. The absorption of compounds whose absorption depends on gastric pH (e.g. ketoconazole, itraconazole, erlotinib etc.) may decrease and the absorption of drugs such as digoxin can increase during treatment with omeprazole. Monitor digoxin levels.

### Adverse Reactions
Increased risk of neonatal intestinal and pulmonary infections.
Hypomagnesaemia.

### Compatibility
- Fluids: Glucose 5%, sodium chloride 0.9%
- Y-site: Cisatracurium, Furosemide, Morphine sulfate, Temocillin

### Incompatibility
- Oral: No information.
- IV: Haloperidol, Lorazepam, midazolam, tacrolimus, tigecycline, vancomycin.

### Stability
**Oral:** Suspension is stable for 30 to 60 days or as per product label. (16) Refrigerate. Protect from light.
**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.
**IV:** Store below 25°C. Protect from light.
Omeprazole
Newborn use only

**Excipients**
- ORAL: Check with hospital pharmacy.
- IV: disodium edetate and sodium hydroxide.

**Special Comments**

**Evidence**

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| **Oral route:** A double blind dose finding trial in neonates found that minimum effective dose depends on gestational age at birth and postnatal age. Optimal dose was higher in older neonates but born very prematurely than in younger neonates born but not prematurely. When studied at 35 weeks post-menstrual age or more, premature neonates of less than 32 weeks required a dose of 2.5 mg/kg/day whereas less premature and term neonates required 1 mg/kg/day. (1) A randomised, double blind, placebo-controlled, crossover design trial of omeprazole therapy was performed by Omari et al in 10 preterm infants (34–40 weeks postmenstrual age). Infants were given omeprazole 0.7 mg/kg daily for 7 days and then placebo for 7 days in randomised order. Compared to placebo, omeprazole therapy significantly reduced gastric acidity, oesophageal acid exposure and number of acid GER episodes. (7) **Intravenous route:** Andersson et al. studied eight patients, aged 8 days to 17 months, receiving intravenous omeprazole at doses of 0.4–1.2 mg/kg. They found that in neonates ≤ 10 days, half-life and clearance of omeprazole were substantially longer and lower than in children. (3) In a randomised trial in paediatric population, 0.5 mg/kg/dose or 1 mg/kg/dose 12 hourly were administered intravenously. Neither of the 2 omeprazole regimens achieved adequate alkalinisation of the gastric pH during the first 24 hours. Between 24 and 48 hours, the 1 mg/kg dose maintained the gastric pH greater than 4 for a greater percentage of the time. (4) Kaufman et al studied 22 paediatric patients ranging in age from 0.9 to 108 months who underwent liver or intestinal transplantation. Intravenous Therapy was started after surgery at 0.5 mg/kg every 12 hours. A dosage of 0.5 mg/kg every 12 hours was sufficient for most patients, but dosing every 6 to 8 hours was required to assure maximal acid suppression in all. (5) Recommended doses of IV omeprazole in paediatric population ranged from 0.5 mg/kg/12 hourly to 1 mg/kg/dose daily. (6) **Treatment of gastrooesophageal reflux disease (GORD)** **NICE Guidelines (8)** 1. Do not offer acid-suppressing drugs, such as proton pump inhibitors (PPIs) or H₂ receptor antagonists (H₂RAs), to treat overt regurgitation in infants and children occurring as an isolated symptom. 2. Consider a 4-week trial of a PPI or H₂RA for infants and young children, and those with a neurodisability associated with expressive communication difficulties who have overt regurgitation with 1 or more of the following: Unexplained feeding difficulties (for example, refusing feeds, gagging or choking), distressed behaviour, faltering growth. **ESPGHAN and NASPGHAN Guidelines (2)** For healing of erosive oesophagitis and relief of GERD symptoms, PPIs are superior to H₂RAs. Both medications are superior to placebo. Administration of long-term acid suppression without a diagnosis is inadvisable. When acid suppression is required, the smallest effective dose should be used. Most patients require only once-daily PPI; routine use of twice-daily dose is not indicated. **Prophylaxis in congenital oesophageal atresia and tracheoesophageal fistula** In a systematic review by Shawyer et al involving 1,663 patients for analysis, most were single centre studies and retrospective; there were no randomised controlled trials. The quality of literature regarding anti-reflux medication for GER post EA-TEF repair is poor. (9) **Pharmacokinetics** PPIs are metabolised by the hepatic cytochrome P450 (CYP) enzyme system. Despite rapid elimination of omeprazole from plasma (i.e. mean elimination half-life = 1 hour), the effect can persist for 24 to 72 hours consequent to strong binding of the active form to its target receptor. Oral bioavailability of omeprazole ranges from 35% to 65% and it is 95% protein bound. (10) Dose may need adjustment if no clinical response. **Safety** Omeprazole is well tolerated clinically and with respect to laboratory tests. There are potential risks including increase of neonatal intestinal and pulmonary infections and occurrence of severe hypomagnesaemia. (1,11-15) **Practice points**
References


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