Omeprazole

Newborn use only

2018

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 B_{12} — 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 Musculoskeletal: Fracture of bone, hip fracture, rhabdomyolysis

	Renal: Acute interstitial nephritis
Compatibility	
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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