Alert	Exposure to H_2 receptor antagonists may be associated with increased risk of NEC, infections and mortality in preterm infants and its use needs to balance safety against risks.
Indication	Treatment of gastroesophageal reflux disease (GORD) Post-operative prophylaxis in congenital tracheoesophageal fistula and oesophageal atresia Prophylaxis to reduce stress gastric ulcers/gastrointestinal haemorrhage Treatment of bradycardias attributed to GOR (not recommended)
Action	Ranitidine is a histamine$_2$ receptor antagonist. Ranitidine decreases acid secretion by inhibiting histamine$_2$ receptors on gastric parietal cells.
Drug Type	Histamine$_2$ receptor antagonist
Trade Name	APO-Ranitidine Tablets [Apotex]; Ausran Tablets [Aspen]; Chemists' Own Ranitidine Forte Tablets [Chemists' Own]; GenRx Ranitidine Tablets [Apotex]; Ranitidine Sandoz Tablets [Sandoz], Zantac Dispersible tablets [Aspen]; Zantac Effervescent tablets [Aspen]; Zantac Syrup [Aspen]; Zantac Tablets [Aspen] Ranitidine Sandoz Injection 50 mg/5 mL [Sandoz]; Zantac Concentrate for injection [Aspen]
Presentation	150 mg tablet 150 mg/10 mL liquid (contains ~7.5% w/v ethanol), 300 mL Zantac: 25 mg/mL, 2 mL injection (50 mg in 2 mL) Ranitidine Sandoz: 10 mg/mL, 5 mL injection (50 mg in 5 mL)
Dosage / Interval	Oral: 2 mg/kg/dose every 8 hours[21] IV Dose:[20] Term neonate — 1.5 mg/kg/dose every 8 hours Preterm (< 37 weeks) neonate — 0.5 mg/kg/dose every 12 hours Continuous IV infusion: 30–60 micrograms/kg/hour[22]
Maximum daily dose	
Route	PO, IV
Preparation/Dilution	**Oral** Administer undiluted. **IV bolus** CAUTION: There are two vial concentrations available. If using the 50 mg/2 mL injection draw up 1 mL (25 mg of ranitidine) and add 9mL of sodium chloride 0.9%, glucose 5% or glucose 10% to make a final volume of 10mL with a concentration of 2.5 mg/mL solution. If using 50 mg/5 mL injection, draw up 2.5 mL (25 mg of ranitidine) and add 7.5mL of sodium chloride 0.9%, glucose 5% or glucose 10% to make a final volume of 10mL with a concentration of 2.5 mg/mL solution. **Continuous infusion** Use the 50 mg/2 mL injection (Zantac) for IV infusion: Draw up 0.2 mL/kg (5 mg/kg of ranitidine) and make up to 50 mL with sodium chloride 0.9%, glucose 5% or glucose 10%. Infuse at a rate of 1 mL/hour = 100 microg/kg/hour Ranitidine Sandoz 50 mg/5 mL injection has no stability data at room temperature and therefore not recommended for IV infusion.
Administration	IV bolus: Administer dose over at least 5 minutes.
Monitoring	Nil
Contraindications	Patients with known hypersensitivity to any component of the preparation.
Precautions	Caution should be observed in patients with hepatic dysfunction since ranitidine is metabolised by the liver. Ranitidine is excreted via the kidneys. In the presence of severe

	renal impairment, plasma concentrations of ranitidine are increased and elimination prolonged. Bradycardia — ensure recommended rates of administration as not exceeded.
Drug Interactions	Amiodarone — concurrent use of amiodarone and ranitidine may result in increased amiodarone exposure.
Adverse Reactions	Exposure to H_2 receptor antagonists may be associated with increased risk of NEC in preterm infants.[8,10,18] The use of ranitidine in infants admitted to the NICU increases the risk of late-onset sepsis.[9,13,19] Use of H_2 blockers was an independent risk factor for *Candida parapsilosis*.[14] Exposure to gastric acid-suppression therapy is associated with health care- and community-associated *Clostridium difficile* infection in children.[5,6] Transient and reversible changes in liver function tests may occur. In some infants, H_2RA therapy causes irritability, head banging, headache, somnolence and other side effects which, if interpreted as persistent symptoms of GERD, could result in an inappropriate increase in dosage. Therapy with gastric acidity inhibitors increases the risk of acute gastroenteritis and community-acquired pneumonia in children.[13]
Compatibility	Fluids: Glucose 5%, glucose 10%, Hartmann's, sodium bicarbonate 4.2%, sodium chloride 0.9% Y-site: Aciclovir, adrenaline (epinephrine) hydrochloride, amifostine, aminophylline, anidulafungin, atracurium, aztreonam, bivalirudin, cefoxitin, ceftaroline fosamil, ciprofloxacin, cisatracurium, dexmedetomidine, dobutamine, dopamine, doripenem, esmolol, ethanol, filgrastim, fluconazole, foscarnet[3], glyceryl trinitrate, granisetron, heparin sodium, labetalol, linezolid, lorazepam, midazolam, milrinone, pancuronium, piperacillin-tazobactam (EDTA-free), remifentanil, tigecycline, vecuronium, zidovudine
Incompatibility	Fluids: TPN Y-site: Caspofungin, levomepromazine, phenobarbitone, sugammadex
Stability	Diluted IV solution using 50 mg/2 mL injection: Stable for 24 hours
Storage	Ampoule: Store below 25°C and protect from light. Tablets: Store below 30°C. Liquid: Store below 25°C.
Special Comments	
Evidence summary	
References	

Original version Date: 24/08/2016	**Author: NMF Consensus Group**
Current Version number: 1.1	**Current Version Date:** 20/02/2017
Risk Rating: Medium	**Due for Review:** 22/08/2020
Approval by: JHCH CQ&PCC	**Approval Date: 22/08/2017**