### Alert
Exposure to H₂ 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 histamine₂ receptor antagonist. Ranitidine decreases acid secretion by inhibiting histamine₂ receptors on gastric parietal cells.

### Drug Type
Histamine₂ 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

**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

### 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 9 mL of sodium chloride 0.9%, glucose 5% or glucose 10% to make a final volume of 10 mL 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 7.5 mL of sodium chloride 0.9%, glucose 5% or glucose 10% to make a final volume of 10 mL 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 H₂ 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 H₂ 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, H₂RA 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

<table>
<thead>
<tr>
<th>Fluids: Glucose 5%, glucose 10%, Hartmann’s, sodium bicarbonate 4.2%, sodium chloride 0.9%</th>
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</thead>
<tbody>
<tr>
<td>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, foscarinet, glycercyl trinitrate, granisetron, heparin sodium, labetolol, linezolid, lorazepam, midazolam, milrinone, pancuronium, piperacillin-tazobactam (EDTA-free), remifentanil, tigecycline, vecuronium, zidovudine</td>
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</tbody>
</table>

### Incompatibility

<table>
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<th>Fluids: TPN</th>
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<tr>
<td>Y-site: Caspofungin, levomepromazine, phenobarbitone, sugammadex</td>
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### 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 |