## Pantoprazole

<table>
<thead>
<tr>
<th>Brand names</th>
<th>Protonix</th>
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<tr>
<td><strong>Medication error potential</strong></td>
<td>ISMP reports that Protonix has been confused with Lotronex and protamine.(^{(2)})</td>
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</tbody>
</table>
| **Contraindications and warnings** | **Contraindications**: Pantoprazole is contraindicated in patients with known hypersensitivity to the formulation or substituted benzimidazole.\(^{(3)}\)  
**Warnings**: Serious reactions such as Stevens-Johnson Syndrome, toxic epidermal necrolysis, and erythema multiforme.\(^{(3)}\) |
| **Infusion-related cautions** | Immediate hypersensitivity reactions, including anaphylaxis, may occur.\(^{(3)}\)  
Thrombophlebitis and injection site reactions have been reported.\(^{(3)}\) |
| **Dosage** | Experience with IV pantoprazole in children, particularly neonates and infants, is limited; currently there is no established IV dose range for pediatric patients.  
Initial pharmacokinetic studies of oral and IV pantoprazole in children 2–16 years of age have found similar pharmacokinetics to that observed in adults.\(^{(4-6)}\) In adults, oral and IV dosages are similar.  
**Doses used in pediatric IV pharmacokinetic studies**: 0.8–1.6 mg/kg/dose, maximum 80 mg/dose and 160 mg/day (children 2–16 years).\(^{(5,6,22)}\)  
**Dosing ranges from pediatric ORAL dosing studies could be extrapolated to IV due to similar kinetics**:  
| Gastroesophageal reflux/reflux esophagitis |  
| Preterm and term neonates and infants: | 1.2 mg/kg/day for ≤6 weeks\(^{(7,8)}\) |
| Children 1 month to 6 years: | 1.2 mg/kg/day provided the same exposure as adults receiving 40 mg.\(^{(9)}\) |
| Children 6–13 years: | 20 mg every day (0.5–1 mg/kg/day) for 28 days\(^{(10)}\) |
| **Adult dosing ranges (IV pantoprazole)** |  
| Gastroesophageal reflux/reflux esophagitis: | 40 mg every day for 7–10 days; oral formulation for maintenance.\(^{(3)}\) |
| Hypersecretory conditions: | 80 mg q 12 hr for up to 6 days; may increase frequency to q 8 hr to suppress acid production.\(^{(3)}\) |
| **Dosage adjustment in organ dysfunction** | No dosage adjustment recommended for renal or hepatic dysfunction.\(^{(3,11)}\) Doses >40 mg/day have not been studied in patients with hepatic dysfunction.\(^{(3)}\) Elimination half-life may be prolonged with hepatic dysfunction.\(^{(12)}\) |
| **Maximum dosage** | 80 mg/dose\(^{(6)}\) and 160 mg/day\(^{(6)}\) in children, 240 mg/day in adults\(^{(3)}\) |
| **Additives** | Edetate disodium (1 mg per 40-mg vial).\(^{(3,13)}\) Edetate disodium is a chelator of metals, and the manufacturer recommends that zinc supplementation should be considered in patients receiving pantoprazole who are prone to zinc deficiency.\(^{(3)}\) |
| **Suitable diluents** | Reconstitute to 4 mg/mL with NS. Further dilution may be done with D5W, LR, NS.\(^{(3,13)}\) |
| **Maximum concentration** | 4 mg/mL\(^{(3,13)}\) |
Pantoprazole

### Preparation and delivery

**Delivery:** Administer via a dedicated line or Y-site administration after flushing the line before and after with a suitable diluent.\(^3\)

**Compatibility:** Observe for any signs of precipitation when administering via Y-site.\(^3\)

### IV push

May administer reconstituted solution of 4 mg/mL in NS over a minimum of at least 2 minutes.\(^3,13\)

### Intermittent infusion

Dilute to 0.4–0.8 mg/mL with suitable diluent and infuse over 15 minutes.\(^3,13\)

### Continuous infusion

Not recommended.\(^3\) In adults, a single IV load of 80 mg followed by 8 mg/hr has been used for 3 days.\(^14-16\)

### Other routes of administration

No information is available to support administration by other routes.

### Comments

**Significant adverse effects:** Administration of proton pump inhibitors (PPIs) has been associated with increased risk of developing gastroenteritis and pneumonia in children.\(^17\)

Adverse effects may include mild elevation of liver function tests.\(^3\)

Prolonged use may lead to impaired absorption of cyanocobalamin (vitamin B\(_{12}\)).\(^18\)

An adult patient developed generalized edema following the initiation of intermittent IV pantoprazole for the treatment of pyloric stenosis.\(^19\) Peripheral edema has been more commonly reported in patients receiving PPIs via continuous infusion of large volumes.

**Pharmacokinetic considerations:** A randomized, open-label, multicenter trial in hospitalized patients 2–16 years of age found the pharmacokinetics of single oral and IV 0.8 or 1.6 mg/kg pantoprazole doses to be similar to doses of 20, 40, or 80 mg in adults. The authors noted that plasma clearance in the children appears to be related to CYP2C19 genotype rather than age.\(^6\)

Another pharmacokinetic study found more rapid clearance in critically ill patients 6 months to 5 years compared to adults.\(^21\)

**Drug interactions:** Pantoprazole is metabolized primarily by CYP2C19 and to a lesser extent by CYP3A4, 2D6, and 2C9. Drug interaction potential is unknown in patients with hepatic dysfunction or in those receiving large doses.\(^3\) Consult appropriate resources for dosing recommendations before combining any drug with pantoprazole.

A known interaction exists between pantoprazole and clopidogrel. Although the manufacturer states no dose adjustment is necessary,\(^3\) pantoprazole may decrease the formation of clopidogrel’s active metabolite and decrease antiplatelet effects.\(^20\)

**Laboratory interference:** False-positive urine tetrahydrocannabinol has been reported in patients taking PPIs, including pantoprazole.\(^3,23\)

### REFERENCES