Protonix Delayed Release Oral Suspension and Tablets (pantoprazole sodium) - Drug Summary

Wyeth Pharmaceuticals Company, a subsidiary of Pfizer Inc.

Jump to Section
- COMMON BRAND NAMES
- THERAPEUTIC CLASS
- DEA CLASS
- ADULT DOSAGE & INDICATIONS
- PEDIATRIC DOSAGE & INDICATIONS
- ▼ View All Sections...

Related Drug Information ▼

Protonix
(pantoprazole sodium)

COMMON BRAND NAMES

Protonix IV, Protonix

THERAPEUTIC CLASS

Proton pump inhibitor (PPI)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Gastroesophageal Reflux Disease

Short-Term Treatment of Erosive Esophagitis Associated w/ GERD:
40mg qd for up to 8 weeks; may consider additional 8-week course if not healed after 8 weeks of treatment

Maint of Healing of Erosive Esophagitis:
40mg qd; no controlled studies beyond 12 months

GERD Associated w/ History of Erosive Esophagitis:
40mg qd by IV infusion for 7-10 days; D/C as soon as patient is able to receive oral formulation

Pathological Hypersecretory Conditions

Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome

40mg bid
Titrate: Adjust to individual needs and continue for as long as clinically indicated; doses up to 240mg have been administered

PEDIATRIC DOSAGE & INDICATIONS

Gastroesophageal Reflux Disease

Short-Term Treatment of Erosive Esophagitis Associated w/ GERD:

≥5 Years:
≥15kg-<40kg: 20mg qd for up to 8 weeks
≥40kg: 40mg qd for up to 8 weeks

ADMINISTRATION

Oral/IV route

Tab/Sus
Do not split, chew, or crush

Tab
Swallow whole, w/ or w/o food
If patients are unable to swallow a 40mg tab, two 20mg tabs may be taken

Sus
Administer approx 30 min ac via oral administration in apple juice or applesauce or NG tube in apple juice only; do not administer in other liquids/foods
Do not divide the 40mg pkt to create a 20mg dosage

Oral Administration in Applesauce:
Sprinkle granules on 1 tsp of applesauce and take w/in 10 min of preparation
Take sips of water to ensure granules are washed down
Oral Administration in Apple Juice:
Empty granules into a small cup or tsp containing 1 tsp of apple juice
Stir for 5 sec and swallow immediately
Rinse container once or twice w/ apple juice and swallow immediately to ensure entire dose is taken
NG Tube/Gastrostomy Tube Administration:
Connect the catheter tip of the syringe to a 16 French (or larger) tube
Empty the contents of the pkt into the barrel of the syringe
Add 10mL (2 tsp) of apple juice and gently tap and/or shake the barrel of the syringe to help rinse the syringe and tube
Repeat at least twice more using the same amount of apple juice each time; no granules should remain in the syringe

IV
Flush IV line before and after administration
15-Min Infusion:
Reconstitute w/ 10mL of 0.9% NaCl and further dilute w/ 80mL of D5W, 0.9% NaCl, or lactated Ringer's inj to a total volume of 100mL w/ a final concentration of approx 0.8mg/mL
May store for up to 6 hrs at room temperature prior to further dilution
Admixed sol must be used w/in 24 hrs from the time of initial reconstitution
Administer over approx 15 min at a rate of approx 7mL/min
2-Min Infusion:
Reconstitute w/ 10mL of 0.9% NaCl to a final concentration of approx 4mg/mL
The reconstituted sol may be stored for up to 24 hrs at room temperature prior to IV infusion
Administer over at least 2 min

HOW SUPPLIED

Inj: 40mg; Sus, Delayed-Release: 40mg (granules/pkt); Tab, Delayed-Release: 20mg, 40mg

WARNINGS/PRECAUTIONS

Symptomatic response does not preclude the presence of gastric malignancy. Acute interstitial nephritis reported; d/c if this develops. May increase risk of *Clostridium difficile*-associated diarrhea (CDAD), especially in hospitalized patients. May increase risk for osteoporosis-related fractures of the hip, wrist, or spine, especially w/ high-dose and long-term therapy. Use lowest dose and shortest duration appropriate to the condition being treated. Hypomagnesemia reported and may require Mg^{2+} replacement and discontinuation of therapy; consider monitoring Mg^{2+} levels prior to and periodically during therapy w/ prolonged treatment. Anaphylaxis and other serious reactions (eg, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis) reported; may require emergency medical treatment. Lab test interactions may occur. (Oral) Atrophic gastritis noted w/ long-term therapy, particularly in patients who were *Helicobacter pylori* positive. Vitamin B12 deficiency caused by hypo- or achlorhydria may occur w/ long-term use (eg, >3 yrs). (IV) Thrombophlebitis reported. Contains EDTA, a chelator of metal ions including zinc; consider zinc supplementation in patients prone to zinc deficiency. Mild, transient transaminase elevations observed in clinical studies.

ADVERSE REACTIONS

Headache, diarrhea, N/V, abdominal pain, flatulence, dizziness, rash, fever, URI, arthralgia.

DRUG INTERACTIONS

Concomitant use w/ atazanavir or nelfinavir is not recommended; may substantially decrease atazanavir or nelfinavir concentrations. Monitor for increases in INR and PT w/ warfarin. May reduce the absorption of drugs where gastric pH is an important determinant of bioavailability; ketoconazole, ampicillin esters, atazanavir, iron salts, erlotinib, mycophenolate mofetil (MMF) absorption may decrease. Caution in transplant patients receiving MMF. Caution w/ digoxin or other drugs that may cause hypomagnesemia (eg, diuretics). May elevate and prolong levels of MTX and/or its metabolite, possibly leading to toxicities; consider temporary withdrawal of therapy w/ high-dose MTX. (IV) Use caution when other EDTA-containing products are also coadministered IV.

PREGNANCY AND LACTATION

Category B, not for use in nursing.

MECHANISM OF ACTION

Proton pump inhibitor; suppresses the final step in gastric acid production by covalently binding to the (H^+/K^+)-ATPase enzyme system at the secretory surface of the gastric parietal cell.

PHARMACOKINETICS

Absorption: Tab: Absolute bioavailability (77%). (40mg) C_{max}=2.5mcg/mL; T_{max}=2.5 hrs; AUC=4.8mcg•hr/mL. IV: (40mg) C_{max}=5.52mcg/mL; AUC=5.4mcg•hr/mL. Sus: Refer to PI. **Distribution:** V_d=11-23.6L; plasma protein binding (98%); (Oral) found in breast milk. **Metabolism:** Liver (extensive) via demethylation, by CYP2C19, w/ subsequent sulfation; oxidation by CYP3A4. **Elimination:** Urine (71%), feces (18%); $T_{1/2}$=1 hr.

ASSESSMENT

Assess for hypersensitivity to the drug, risk for osteoporosis-related fractures, pregnancy/nursing status, and possible drug interactions. Obtain baseline Mg^{2+} levels. (IV) Assess if prone to zinc deficiency.

MONITORING

Monitor for signs/symptoms of acute interstitial nephritis, CDAD, bone fractures, hypersensitivity reactions, and other adverse reactions. Monitor Mg^{2+} levels periodically. Monitor INR and PT when given w/ warfarin. (Oral) Monitor for signs/symptoms of atrophic gastritis and vitamin B12 deficiency. (IV) Monitor for thrombophlebitis, zinc deficiency, and transaminase elevations.

PATIENT COUNSELING

Instruct to take ud. Inform of the most frequently occurring adverse reactions. Instruct to inform physician if any unusual symptom develops, or if any known symptom persists or worsens; advise to immediately report and seek care for any cardiovascular or neurological symptoms (eg, palpitation, dizziness, seizures, tetany) and for diarrhea that does not improve. Instruct to inform physician of all medications currently being taken, including OTC medications, as well as allergies to any medications. Inform that concomitant administration of antacids does not affect the absorption of the tabs. Advise that oral sus pkt is a fixed dose and cannot be divided to make smaller dose.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). (IV) Protect from light.

Back to top