Protonix® I.V. (pantoprazole) – Expanded indication

- On August 12, 2024, the FDA approved Pfizer's Protonix I.V. (pantoprazole), for treatment of gastroesophageal reflux disease (GERD) and a history of erosive esophagitis (EE) for up to 10 days in adults and *up to 7 days in pediatric patients 3 months and older*.
    - Protonix I.V. was previously approved for short-term treatment (7 to 10 days) of adult patients with GERD and a history of EE.
- Protonix I.V. is also approved for treatment of pathological hypersecretory conditions including Zollinger-Ellison Syndrome in adults.
- The approval of Protonix I.V. for the expanded indication was supported by evidence from adequate and well-controlled studies of intravenous and oral pantoprazole sodium in adults and oral pantoprazole sodium in pediatric patients, with additional pharmacokinetic and safety data of intravenous pantoprazole in pediatric patients 1 year of age and older and oral pantoprazole in pediatric patients 3 months of age and older.
- The recommended dose of Protonix I.V. for the treatment of pediatric patients 3 months of age and older is based on age and actual body weight.
- Refer to the Protonix I.V. drug label for complete dosing and administration recommendations for both pediatric and adult patients.