Voquezna® (vonoprazan) – New indication

- On July 18, 2024, Phathom Pharmaceuticals announced the FDA approval of Voquezna (vonoprazan), for the relief of heartburn associated with non-erosive gastroesophageal reflux disease (GERD) in adults.

- Voquezna is also approved:

  - for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
  - To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
  - In combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults
  - In combination with amoxicillin for the treatment of *H. pylori* infection in adults.

- The approval of Voquezna for the new indication was based on a randomized, placebo-controlled, double-blind study in 772 adult patients with a diagnosis of symptomatic non-erosive GERD. Patients were randomized to one of the following treatment groups in the 4-week placebo-controlled phase: Voquezna 10 mg once daily, a higher dosage of Voquezna, or placebo once daily. The primary endpoint was the percentage of 24-hour heartburn-free days, as assessed by daily diary over 4 weeks.

  - The least squares mean percentage of 24-hour heartburn-free days was 45% with Voquezna 10 mg vs. 28% with placebo (difference 17, 95% CI: 12, 22; $p < 0.001$).
  - The higher Voquezna dose group did not demonstrate additional treatment benefit compared to Voquezna 10 mg once daily through week 4.

- The most common adverse reactions (≥ 2%) with Voquezna use for non-erosive GERD were abdominal pain, constipation, diarrhea, nausea, and urinary tract infection.

- The recommended dose of Voquezna for non-erosive GERD is 10 mg once daily for 4 weeks.

  - Refer to the Voquezna drug label for dosing for all its other indications.