

Voquezna[®] (vonoprazan) – New indication

- On July 18, 2024, <u>Phathom Pharmaceuticals announced</u> the FDA approval of <u>Voquezna</u> (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.



At Optum, we help create a healthier world, one insight, one connection, one person at a time. All Optum trademarks and logos are owned by Optum, Inc., in the U.S. and other jurisdictions. All other trademarks are the property of their respective owners. This document contains information that is considered proprietary to Optum Rx and should not be reproduced without the express written consent of Optum Rx. RxNews[®] is published by the Optum Rx Clinical Services Department.