Vonoprazan FDA Approved for Heartburn Relief Associated with Non-Erosive Gastroesophageal Reflux Disease

A large portion of the population of patients in the United States with GERD have the non-erosive type of the disease.

Vonoprazan (Voquezna; Phantom Pharmaceuticals) tablets have been approved by the FDA in adults for the relief of heartburn associated with non-erosive gastroesophageal reflux disease (GERD), according to a news release from Phantom Pharmaceuticals.[1]

Non-erosive GERD is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions. The subtype is the largest category of GERD, and affects an estimated 45 million US adults, of which 15 million are treated with an annual prescription medicine.[1]

A large portion of the population of patients in the United States with GERD have the non-erosive type of the disease, which affects millions of individuals who suffer from consistent heartburn.[1]

Vonoprazan was previously approved by the FDA in November 2023 for the treatment of all grades of erosive GERD. This was the first major innovation to treat erosive GERD in the US in over 3 decades.[2] The drug is also approved in combination with antibiotics to treat *Helicobacter pylori* infection.[1]

“This approval provides patients and health care providers with immediate access to the first and only FDA-approved treatment of its kind, from a new class of acid suppression therapy, and the power to help provide complete 24-hour heartburn-free days and nights,” Terrie Curran, president and chief executive officer of Phantom, said in the news release.[1]

Non-erosive GERD is characterized by reflux-related symptoms in the absence of esophageal mucosal erosions. The subtype is the largest category of GERD, and affects an estimated 45 million US adults, of which 15 million are treated with an annual prescription medicine.[1]

The approval of vonoprazan was based in part on the positive results from the PHALCON-NERD-301 study, a phase 3 randomized, placebo-controlled, multi-site study in the US that evaluated the safety and efficacy of the drug for the daily treatment of adults with non-erosive GERD.[1]

In the study conducted by Laine et al., among 772 randomized subjects, the percentage of 24-hour heartburn-free days was 44.8% for participants taking 10 mg vonoprazan and 27.7% for those prescribed a placebo.[3]

This benefit began to appear as early as the first day of therapy with vonoprazan. Laine et al. found that the differences in percentages of subjects with a 24-hour heartburn-free day for vonoprazan – in the 10 mg and 20 mg dosages – compared to placebo were 8.3% and 11.6% on day 1 and 18.1% and 23.2% on day 2, respectively.[3]

The most common adverse reactions (≥2%) in participants treated with vonoprazan reported during the trial included constipation, abdominal pain, nausea and urinary tract infection. Additionally, in the 20-week extension phase of the trial, some patients reported upper respiratory tract infection and sinusitis.[1]

“The pivotal study that led to this approval showed that vonoprazan significantly reduced heartburn episodes in patients with non-erosive GERD along with an established safety profile,” Colin W. Howden, MD, professor emeritus at the University of Tennessee, said in the news release. “Today’s approval of VOQUEZNA provides physicians with a novel, first-in-class treatment that can quickly and significantly reduce heartburn for many adult patients.”[1]

References

1. Phantom Pharmaceuticals. Phathom Pharmaceuticals announces FDA approval of VOQUEZNA® (vonoprazan) tablets for the relief of heartburn associated with non-erosive GERD in adults. News release. Released July 18, 2024. Accessed July 18, 2024. https://investors.phathompharma.com/news-releases/news-release-details/phathom-pharmaceuticals-announces-fda-approval-voqueznar-0
2. Ferruggia K. FDA approves Vonoprazan for erosive GERD. Pharmacy Times. Published November 2, 2023. Accessed July 18, 2024. https://www.pharmacytimes.com/view/fda-approves-vonoprazan-for-erosive-gerd
3. Laine L, Spechler S, Yadlapati R, et al. Vonoprazan is efficacious for treatment of heartburn in non-erosive reflux disease: a randomized trial. *Clin Gastro Hepatol*. 2024. doi:10.1016/j.cgh.2024.05.004

News Source:

https://www.pharmacytimes.com/view/vonoprazan-fda-approved-for-heartburn-relief-associated-with-non-erosive-gastroesophageal-reflux-disease