

Voquezna[™] Triple Pak[™] (vonoprazan, amoxicillin, clarithromycin), Voquezna Dual Pak[™] (vonoprazan, amoxicillin) – New drug approval

- On May 3, 2022, [Phantom Pharmaceuticals announced](#) the FDA approval of [Voquezna Triple Pak \(vonoprazan, amoxicillin, clarithromycin\)](#) and [Voquezna Dual Pak \(vonoprazan, amoxicillin\)](#), for the treatment of *Helicobacter pylori* (*H. pylori*) infection in adults.
- As a result of chronic inflammation induced by *H. pylori* infection, infected patients may develop a range of pathologies including dyspepsia, peptic ulcer disease, non-cardia gastric cancer, and mucosa-associated lymphoid tissue lymphoma.
 - *H. pylori* is estimated to affect ~115 million people in the U.S.
 - The standard of care includes an acid suppressive agent (eg, proton pump inhibitor [PPI]) used in combination with antibiotic therapy.
- Voquezna contains vonoprazan, a novel potassium-competitive acid blocker. Vonoprazan has shown the potential to provide acid suppression that can achieve pH levels that are important in enhancing antibiotic effectiveness.
- The efficacy of Voquezna Triple Pak and Dual Pak were established in a randomized, controlled, double-blind triple therapy/open-label dual therapy study in treatment-naïve *H. pylori*-positive adult patients. Patients were randomized to Voquezna Triple Pak, Voquezna Dual Pak, or a PPI (lansoprazole) plus amoxicillin plus clarithromycin (LAC) administered for 14 consecutive days. The primary endpoint was eradication rates of *H. pylori* at test-of-cure (≥ 27 days post-therapy).
 - Voquezna Triple Pak and Voquezna Dual Pak were shown to be noninferior to LAC in patients who did not have a clarithromycin or amoxicillin resistant strain of *H. pylori* at baseline (eradication rates: 84.7%, 78.5%, and 78.8%, respectively).
 - Voquezna Triple Pak and Voquezna Dual Pak were shown to be superior to LAC in patients who had a clarithromycin resistant strain of *H. pylori* at baseline (eradication rates: 65.8%, 69.6%, and 31.9%, respectively) and in the overall population (eradication rates: 80.8%, 77.2%, and 68.5%, respectively).
- Voquezna Triple Pak and Dual Pak are contraindicated in patients with hypersensitivity reactions to individual components of the products and in patients taking rilpivirine-containing products.
- Additional contraindications to Voquezna Triple Pak (due to the clarithromycin component) include drug interactions (refer to drug label for complete details) and in patients with a history of cholestatic jaundice or hepatic dysfunction associated with prior use of clarithromycin.
- Warnings and precautions for Voquezna Triple Pak and Dual Pak include hypersensitivity reactions, severe cutaneous adverse reactions, *Clostridioides difficile*-associated diarrhea, rash in patients with mononucleosis, interactions with diagnostic investigations for neuroendocrine tumors, and development of drug-resistant bacteria.
- Additional warnings and precautions for Voquezna Triple Pak (due to the clarithromycin component) include QT prolongation, hepatotoxicity, serious adverse reactions due to concomitant use of clarithromycin with other drugs, embryo-fetal toxicity, and exacerbation of myasthenia gravis.

- The most common adverse reactions ($\geq 2\%$) with Voquezna Triple Pak use were dysgeusia, diarrhea, vulvovaginal candidiasis, headache, abdominal pain, and hypertension.
- The most common adverse reactions ($\geq 2\%$) with Voquezna Dual Pak use were diarrhea, abdominal pain, vulvovaginal candidiasis and nasopharyngitis.
- The recommended adult oral dosage of Voquezna Triple Pak is vonoprazan 20 mg plus amoxicillin 1,000 mg plus clarithromycin 500 mg, each given twice daily (in the morning and evening, 12 hours apart), with or without food, for 14 days.
- The recommended adult oral dose of Voquezna Dual Pak is vonoprazan 20 mg given twice daily (in the morning and evening) plus amoxicillin 1,000 mg three times daily (in the morning, mid-day, and evening), with or without food, for 14 days.
- Phantom Pharmaceuticals plans to launch Voquezna Triple Pak and Dual Pak in the third quarter of 2022.
- Voquezna Triple Pak will be available as a carton of 14 daily administration packs for morning and evening dosing, each containing the following three drug products: vonoprazan 20 mg tablets, clarithromycin 500 mg tablets, and amoxicillin 500 mg capsules.
- Voquezna Dual Pak will be available as a carton of 14 daily administration packs for morning, mid-day and evening dosing, each containing the following two drug products: vonoprazan 20 mg tablets and amoxicillin 500 mg capsules.



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