



June 5, 2023

FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults

On May 25th, 2023, the U.S. Food and Drug Administration (FDA) approved the oral antiviral Paxlovid[®] (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) for the treatment of mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19, including hospitalization or death.

Paxlovid[®] is the fourth drug—and first oral antiviral pill—approved by the FDA to treat COVID-19 in adults.

Paxlovid[®], manufactured and packaged under the emergency use authorization (EUA) and distributed by the [U.S. Department of Health and Human Services](#), will continue to be available to ensure ongoing access for adults, as well as treatment of eligible children 12-18 years of age who are not covered by the May 25th approval. Paxlovid[®] is not approved or authorized for use as a pre-exposure or post-exposure prophylaxis for prevention of COVID-19.

Safety and Efficacy Data:

The efficacy of Paxlovid[®] was primarily supported by the final results of the [EPIC-HR clinical trial](#). EPIC-HR was a randomized, double-blind, placebo-controlled clinical trial studying Paxlovid[®] for the treatment of non-hospitalized symptomatic adults with a laboratory confirmed diagnosis of SARS-CoV-2 infection. Patients were adults 18 years of age and older with a pre-specified risk factor for progression to severe disease or were 60 years and older regardless of pre-specified chronic medical conditions. All patients had not received a COVID-19 vaccine and had not been previously infected with COVID-19. Paxlovid[®] significantly reduced the proportion of people with COVID-19 related hospitalization or death from any cause through 28 days of follow-up by 86% compared to placebo among patients treated within five days of symptom onset and who did not receive COVID-19 therapeutic monoclonal antibody treatment. In this analysis, 977 patients received Paxlovid[®], and 989 patients received placebo, and among these patients, 0.9% who received Paxlovid[®] were hospitalized due to COVID-19 or died from any cause during 28 days of follow-up compared to 6.5% of the patients who received the placebo.

Benefit of Paxlovid[®] was also observed in patients with prior immunity to the virus that causes COVID-19. Among patients in EPIC-HR who were antibody-positive at trial enrollment, the risk of COVID-19-related hospitalization or death from any cause during 28 days of follow-up was 0.2% among the 490 patients treated with Paxlovid[®] compared with 1.7% of the 479 patients receiving placebo. EPIC-SR was another clinical trial that enrolled vaccinated patients with at least one risk factor for progression to severe COVID-19. Although not statistically significant, among these vaccinated patients, there was a reduction in the risk of COVID-19 related hospitalization or death from any cause.

EPIC-HR and EPIC-SR were randomized controlled trials and provide information about COVID-19 rebound. Data from these two trials showed that rebound in SARS-CoV-2 (RNA or virus) shedding or COVID-19 symptoms occurred in a subset of patients and happened in both the patients receiving Paxlovid[®] and the placebo. Based on the data currently available to the FDA, there is not a clear association between Paxlovid[®] treatment and COVID-19 rebound.

Because of the importance of reducing the risk of significant drug-drug interactions with Paxlovid[®], the [approved label](#) and authorized [Fact Sheet for Health Care Providers](#) for the Paxlovid[®] EUA come with a boxed warning with instructions for prescribers. Prescribers should review all medications taken by the patient to

assess for potential drug-drug interactions and determine if other medicines that a patient may be taking require a dose adjustment, interruption and/or additional monitoring. Prescribers should consider the benefit of Paxlovid® treatment in reducing hospitalization and death, and whether the risk of potential drug-drug interactions for an individual patient can be appropriately managed.

In conjunction with the May 25th approval, the FDA is providing all prescribers with important information for prescribing Paxlovid® properly and safely, such as dosing instructions, potential side effects and information regarding drugs that may cause drug-drug interactions with Paxlovid®. The most common side effects of taking Paxlovid® include impaired sense of taste and diarrhea. Patients should discuss with their health care provider whether Paxlovid® is right for them.

Clinician Resources:

- Fact Sheet: [Healthcare Providers](#)
- Fact Sheet: [Patients, Parents and Caregivers](#)
- [Paxlovid® Eligibility Screening Checklist](#)
- [Paxlovid® Drug Interaction Checker](#)
- [COVID-19 Test to Treat Locator](#)
- [Frequently Asked Questions: FDA EUA for Paxlovid® \(FDA\)](#)

References:

1. U.S. Food and Drug Administration. [FDA Approves First Oral Antiviral for Treatment of COVID-19 in Adults](#). Published online May 25, 2023
2. Department of Health and Humans Services. Administration for Strategic Preparedness and Response. [Paxlovid \(nirmatrelvir co-packaged with ritonavir\)](#). Available online.