



March 14, 2024

**IMPORTANT PRESCRIBING AND DISPENSING INFORMATION  
FOR PAXLOVID (NIRMATRELVIR TABLETS; RITONAVIR TABLETS)**

Subject: Discontinuation of EUA-labeled packaging for PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets); and continuation of EUA status for eligible pediatric patients.

Dear Healthcare Provider,

The purpose of this letter is to make you aware that EUA-labeled PAXLOVID packaging presentation (two-dose blister cards) is no longer authorized for emergency use, regardless of the labeled or extended expiration date. The 5-day treatment course of PAXLOVID will now be available only in the NDA-approved single-dose blister package presentation; (see table below). The PAXLOVID EUA will continue to authorize the emergency use of the NDA-approved single-dose blister package presentation of PAXLOVID for the treatment of mild-to-moderate COVID-19 in pediatric patients 12 years of age and older weighing at least 40 kg who are at high risk for progression to severe COVID-19, including hospitalization or death.

Under NDA, PAXLOVID is approved for use in adults, and under EUA, PAXLOVID is authorized for use in pediatric patients (12 years of age and older weighing at least 40 kg). **The NDA-approved packaging presentations (single-dose blister cards) can be dispensed for use in the EUA authorized pediatric population or NDA approved adult population.**



NDA packaging presentation (ten single-dose blister cards) for patients with normal renal function or mild renal impairment (eGFR  $\geq 60$  to  $< 90$  mL/min)



**Morning Dose:**  
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together



**Bedtime Dose:**  
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together



NDA packaging presentation (ten single-dose blister cards) for patients with moderate renal impairment (eGFR  $\geq 30$  to  $< 60$  mL/min)



**Morning Dose:**  
Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together.



**Bedtime Dose:**  
Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together.



## **HEALTHCARE PROVIDER ACTIONS:**

- The NDA-approved packaging presentations (single-dose blister card) can be dispensed for use in the EUA authorized pediatric patient population or NDA approved adult population.
- EUA-labeled PAXLOVID must be returned to the manufacturer or disposed of in accordance with all federal, state, and local regulations.
- Counsel patients on how the tablets are labeled on the blister pack and instruct them how to take each dose and how to complete their medication regimen.
- Always refer patients to the most recent version of the Patients, Parents and Caregivers EUA Fact Sheet or the FDA approved patient labeling (Patient Information) available on [PAXLOVID™ | Pfizer](#).
- Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID and the dosage form, as follows:
  - PAXLOVID Tablets 300 mg; 100 mg Dose Pack- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) - for patients with normal renal function or mild renal impairment (eGFR  $\geq 60$  to  $< 90$  mL/min), or
  - PAXLOVID Tablets 150 mg; 100 mg Dose Pack- 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) for patients with moderate renal impairment (eGFR  $\geq 30$  to  $< 60$  mL/min);
- Stay current with the latest EUA Fact Sheet for Healthcare Providers [PAXLOVID™ | Pfizer](#).
- See the current prescribing information and EUA Fact Sheet for Healthcare Providers for clinically significant drug interactions, including contraindicated drugs. Before prescribing PAXLOVID, the Healthcare Provider should carefully review the patient's current medications to assess for a potential drug interaction with PAXLOVID. You should also inform patients that PAXLOVID may interact with some drugs and is **contraindicated** for use with some drugs; therefore, patients should be advised to communicate the use of any prescription or non-prescription medications or herbal products to their Healthcare Provider.

[Prescribing Information \(including BOXED WARNING\)](#)  
[EUA Fact Sheet for Healthcare Providers](#)

Under NDA, PAXLOVID is approved for use in certain adults for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death.

PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in pediatric patients 12 years of age and older weighing at least 40 kg who are at high risk for progression to severe COVID-19, including hospitalization or death; and

The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

## **Reporting Serious Adverse Events and Medication Errors:**

Under the EUA, all serious adverse events and medication errors potentially related to PAXLOVID use in the authorized pediatric population must be reported within 7 calendar days from the healthcare provider's awareness of the event.

Serious adverse event reports and medication error reports should be submitted to FDA's MedWatch program using one of the following methods:

- Complete and submit the report online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm), or
- Complete and submit a postage-paid Form FDA 3500 (<https://www.fda.gov/media/76299/download>) and return by:
  - Mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or
  - Fax (1-800-FDA-0178)
- Call 1-800-FDA-1088 to request a reporting form.
- Please provide a copy of all FDA MedWatch forms to Pfizer via fax (1-866-635-8337), telephone (1-800-438-1985) or website [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com)

The PAXLOVID EUA Fact Sheet for Healthcare Providers is available at [www.COVID19oralRx.com](http://www.COVID19oralRx.com) or by scanning the QR Code below:



Sincerely,