April 14, 2022

**IMPORTANT DISPENSING INFORMATION**

Subject: PAXLOVID™ Emergency Use Authorization (EUA) Updates: new additional packaging configuration to be used for dosing and dispensing in patients with moderate renal impairment; different ritonavir tablet appearance.

Dear Healthcare Provider,

The purpose of this letter is to alert providers to the availability of a **new additional PAXLOVID 150 mg;100 mg Dose Pack** packaging configuration for use in patients with moderate renal impairment. PAXLOVID contains two different drugs (nirmatrelvir and ritonavir) that are co-packaged in a daily blister card for oral use.

PAXLOVID is now available in the following **two packaging configurations**.

1. **PAXLOVID 300 mg;100 mg Dose Pack:** This packaging configuration should be used for patients with normal renal functions or mild renal impairment **(eGFR* greater than 60 ml/min).**

   Each 300 mg;100 mg Dose Pack includes 5 daily blister cards, each containing a morning and evening dose, with each dose consisting of 300 mg nirmatrelvir (two oval, pink 150 mg tablets) and 100 mg ritonavir (one white or white to off-white film-coated 100 mg tablet uniquely identified by the color, shape, and debossing)†.

2. **PAXLOVID 150 mg;100 mg Dose Pack:** This packaging configuration should be used for patients with moderate renal impairment **(eGFR ≥30 to <60 mL/min).**

   Each 150 mg;100 mg Dose Pack includes 5 daily blister cards, each containing a morning and evening dose, with each dose consisting of 150 mg nirmatrelvir (one oval, pink 150 mg tablet) and 100 mg ritonavir (one white or white to off-white film-coated 100 mg tablet uniquely identified by the color, shape, and debossing) †.

PAXLOVID is not recommended (the appropriate dose has not been determined) in patients with severe renal impairment (<30 mL/min).

*eGFR=estimated glomerular filtration rate based on the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula
†Refer to Section 16, How Supplied/Storage and Handling, of the Fact Sheet for Healthcare Providers, for detailed description of the tablets.

In addition, healthcare providers should be aware of the **possibility of differences in the ritonavir tablet appearance**, including shape, color, and debossing. Depending on the package, the ritonavir tablet may appear as:

- White film-coated ovaloid tablets debossed with the “a” logo and the code NK.
  Or
- White to off-white, capsule-shaped, film-coated tablets debossed with “H” on one side and “R9” on the other side.

## HEALTHCARE PROVIDER ACTION

- **When prescribing PAXLOVID, always specify the numeric dose for each active ingredient within PAXLOVID as follows**:
    - PAXLOVID 300 mg;100 mg Dose Pack for patients with normal renal function or mild renal impairment, or
    - PAXLOVID 150 mg;100 mg Dose Pack for patients with moderate renal impairment

- Only dispense the PAXLOVID 150 mg;100 mg Dose Pack that contains 150 mg nirmatrelvir and 100 mg ritonavir, when dispensing PAXLOVID for patients with moderate renal impairment.

- In the event that the Paxlovid 150 mg;100 mg dose pack is unavailable; pharmacist should refer to the provided instructions entitled "IMPORTANT PAXLOVID™ EUA DISPENSING INFORMATION FOR PATIENTS WITH MODERATE RENAL IMPAIRMENT" for dispensing of PAXLOVID to patients with moderate renal impairment *[see Dosage and Administration (2.2)]*.

- Be aware of the differences in the ritonavir tablet debossing and color and counsel patients as appropriate.

- Stay current with the latest Fact Sheets for Health Care Providers (www.COVID19oralRx.com)

## Indication & Authorized Use:

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 adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS CoV-2 viral testing, and who are at high-risk for progression to severe COVID-19, including hospitalization or death.

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.

For information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the Centers for Disease Control and Prevention (CDC) website: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.

Healthcare providers should consider the benefit-risk for an individual patient.

## Limitations of Authorized Use:

- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.
- PAXLOVID is not authorized for pre-exposure or post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use for longer than 5 consecutive days.

PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).

Patients requiring hospitalization due to severe or critical COVID-19 after starting treatment with PAXLOVID may complete the full 5-day treatment course per the healthcare provider's discretion.

**Reporting Adverse Events and Medication Errors:**

Under the EUA, all serious adverse events and all medication errors potentially related to PAXLOVID must be reported.
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, 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 208529787, or by fax (1-800-FDA-0178), or
- 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

The PAXLOVID EUA Fact Sheet for Healthcare Providers is available at www.COVID19oralRx.com or by scanning the QR Code below:

Sincerely,

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