DATE

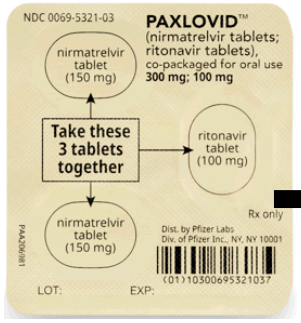
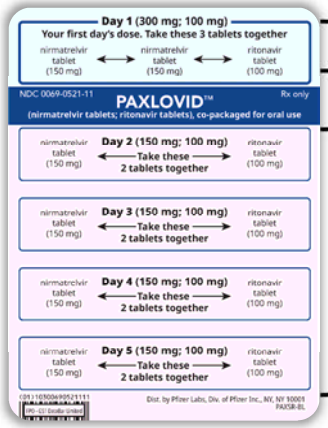
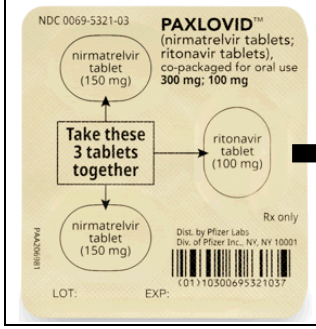
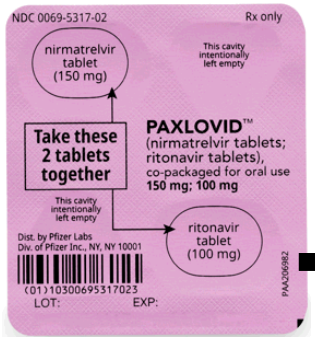
IMPORTANT PRESCRIBING AND DISPENSING INFORMATION
FOR PAXLOVID™ (NIRMATRELVIR TABLETS; RITONAVIR TABLETS)

Subject: Availability of a new additional packaging configuration for PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets); to be used for dosing and dispensing in patients with **severe** renal impairment.

Dear Healthcare Provider,

The purpose of this letter is to alert providers to the availability of a **new additional PAXLOVID Dose Pack** packaging configuration for use in patients with **severe** renal impairment (eGFR <30 mL/min) and is administered once daily. PAXLOVID contains two different drugs (nirmatrelvir and ritonavir) that are co-packaged in a blister card for oral use.

PAXLOVID is now available in the following three packaging configurations:

For patients with **normal renal function or mild renal impairment** (eGFR ≥60 to <90 mL/min) NDA packaging presentation (ten single-dose blister cards)	For patients with **moderate renal impairment** (eGFR ≥30 to <60 mL/min) NDA packaging presentation (ten single-dose blister cards)	For patients with **severe renal impairment** (eGFR <30 mL/min) NDA packaging presentation (single blister card)
		
 **Morning Dose:** Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together 	 **Morning Dose:** Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together. 	 **Day 1 Dose:** Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together once  **Days 2-5 Dose:** Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together once daily. 
 **Bedtime Dose:** Take the 2 pink nirmatrelvir tablets 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:

- Paxlovid is administered **once daily** for **patients with severe renal impairment** (eGFR <30 mL/min). On days of hemodialysis, the PAXLOVID dose should be administered after hemodialysis.

- 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 ≥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 ≥30 to <60 mL/min); or

    - **PAXLOVID Tablets 300 mg; 100 mg (Day 1)** and **150 mg; 100 mg (Days 2-5) Dose Pack** – 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) **once** on day 1 followed by 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) **once daily** on days 2-5 **for patients with severe renal impairment** (eGFR <30 mL/min).

- **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.**

- 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 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 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, 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

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

The PAXLOVID US Prescribing Information is available at www.PAXLOVID.com or by scanning the QR Code below:

Sincerely,