November 1, 2023

IMPORTANT PRESCRIBING AND DISPENSING INFORMATION

Subject: Availability of TWO different packaging presentations for PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets).

Dear Healthcare Provider,

The purpose of this letter is to make you aware of the availability of a new packaging presentation for PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets) under the recently approved New Drug Application (NDA) and the differences between the Emergency Use Authorization (EUA) packaging and the FDA approved NDA packaging presentation.

The new packaging presentation is single dose blister cards that is intended to simplify the administration of the product and maximize the safe use of the product.

Under NDA, PAXLOVID is approved for use in certain adults, and under EUA, PAXLOVID is authorized for use in certain adults and adolescents. Either the NDA-approved or EUA-labeled packaging presentations may be dispensed for use in the authorized or approved adult or adolescent populations.

A treatment course of PAXLOVID (5 days) will now be available in two presentations; single-dose and two-dose blister cards (see table below). Although the packaging differs, the medicine contained in the blister cards is the same.
EUA packaging presentation (two-dose blister cards) for patients with normal renal function or mild renal impairment (eGFR ≥60 to <90 mL/min)

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

Morning Dose:
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time.

Evening Dose:
Take the 2 pink nirmatrelvir tablets and 1 white to off-white ritonavir tablet together at the same time.

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
EUA packaging presentation (two-dose blister cards) for patients with moderate renal impairment (eGFR ≥30 to <60 mL/min)

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

Evening Dose:
Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together at the same time.

New NDA packaging presentation (single-dose blister cards) for patients with moderate renal impairment (eGFR ≥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:

- Based on the packaging presentation dispensed, counsel patients on how the tablets are labeled on the blister pack and teach them how to take each dose and how to complete their medication regimen.

- Always dispense the most recent version of the Patients, Parents and Caregivers EUA Fact Sheet or the FDA approved patient labeling (Patient Information).

- 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);

- Stay current with the latest EUA Fact Sheet for Healthcare Providers (www.COVID19oralRx.com).
- 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

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:

Sincerely,

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