DATE

IMPORTANT DISPENSING INFORMATION

Subject: Extension of shelf life from 9 months to 12 months for PAXLOVID™ Emergency Use Authorization (EUA).

Dear Healthcare Provider,

The purpose of this letter is to notify you that the U.S. Food and Drug Administration (FDA) approved a shelf-life extension for PAXLOVID from 9 months to 12 months for lots referenced below.

You may have already received some lots of PAXLOVID labeled with the 9-month shelf life that were manufactured prior to FDA issuance of the EUA that authorized 12-month expiry. These lots can be used for an additional 3 month of shelf life (increased from 9 months to 12 months) when stored according to storage and handling requirements detailed in the Fact Sheet for Health Care Providers. This extension has been approved by FDA. Please do not discard PAXLOVID labeled with 9-month shelf life as it can continue to be used for an additional 3 months beyond the labeled date, these apply to only the select lot numbers as detailed in the table below.

Lot/Batch#	Labeled Expiration date	Extended Expiration Date
FL4516	07/31/22	10/31/22
FL4517	07/31/22	10/31/22
FR7229	07/31/22	10/31/22
FR9088	08/31/22	11/31/22

Indication & Authorized Use:

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product PAXLOVID for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

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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