August 05, 2022

**IMPORTANT PRESCRIBING AND DISPENSING INFORMATION**

Subject: Minimizing wrong dose medication errors and revised Patients, Parents and Caregivers Fact Sheet for PAXLOVID (nirmatrelvir tablets; ritonavir tablets).

Dear Healthcare Provider,

The purpose of this letter is to make you aware of wrong-dose medication errors associated with PAXLOVID (nirmatrelvir tablets; ritonavir tablets), provide a reminder about the two PAXLOVID dose packs and inform you of the availability of a revised PAXLOVID Patients, Parents and Caregivers Fact Sheet (PFS) to be dispensed with each PAXLOVID prescription.

Pfizer has become aware of reports of wrong-dose medication errors that have occurred with Paxlovid. These wrong-dose errors have occurred during prescribing, dispensing, and administration. Many of these errors have occurred during patient self-administration and generally involved patients incorrectly taking the wrong combination of nirmatrelvir tablets and ritonavir tablets from the blister card leading to wrong-dose medication errors.

Pfizer has revised the PAXLOVID Patients, Parents and Caregivers Fact Sheet to address wrong dose medication errors that occur during patient self-administration. The revised Fact Sheet will show how the medication is labeled and inform the patient on how to correctly take Paxlovid. Each dispensed prescription for Paxlovid should include a Patients, Parents and Caregivers Fact Sheet.

As a reminder, PAXLOVID contains two different drugs (nirmatrelvir tablets and ritonavir tablets) that are co-packaged in a daily blister card for oral use.

PAXLOVID is available in the following two packaging configurations.

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

   The 300 mg; 100 mg Dose Pack is a carton containing 5 daily blister cards. Each blister card contains a daily morning dose and evening dose, with each dose consisting of **300 mg nirmatrelvir** (two oval, pink 150 mg tablets) and **100 mg ritonavir** (one white to off-white film-coated 100 mg tablet).

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

   The 150 mg; 100 mg Dose Pack is a carton containing 5 daily blister cards. Each blister card contains a daily morning dose and evening dose, with each dose consisting of **150 mg nirmatrelvir** (one oval, pink 150 mg tablet) and **100 mg ritonavir** (one white to off-white film-coated 100 mg tablet).

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

| |
|---|
| PAXLOVID is not recommended in patients with severe hepatic impairment (Child-Pugh Class C) as no pharmacokinetic or safety data is available in subjects with severe hepatic impairment. |

*eGFR=estimated glomerular filtration rate based on the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) formula

**HEALTHCARE PROVIDER ACTIONS:**

- Use the PAXLOVID **150 mg; 100 mg** Dose Pack only when prescribing or dispensing PAXLOVID for patients with **moderate renal impairment** (eGFR ≥30 to <60 mL/min).
- When prescribing PAXLOVID, always specify the numeric dose for each active ingredient within PAXLOVID as follows:
    - PAXLOVID 300 mg; 100 mg Dose Pack- 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir for patients with normal renal function or mild renal impairment, or
    - PAXLOVID 150 mg; 100 mg Dose Pack- 150 mg nirmatrelvir with 100 mg ritonavir for patients with moderate renal impairment (eGFR ≥30 to <60 mL/min)

- **Always dispense the most recent version of Patients, Parents and Caregivers Fact Sheet with each prescription**.

- Counsel patients on how the medication is labeled on the blister pack, and teach them about the two different medications that they will be taking twice a day

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

**Emergency Use Authorization (EUA):**

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/hcp/clinical-care/underlyingconditions.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 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.

PAXLOVID may also be prescribed for an individual patient by a state-licensed pharmacist under the following conditions:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and
- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

The state-licensed pharmacist should refer an individual patient for clinical evaluation (e.g., telehealth, in-person visit) with a physician, advanced practice registered nurse, or physician assistant licensed or authorized under state law to prescribe drugs, if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- PAXLOVID is not an appropriate therapeutic option based on the authorized Fact Sheet for Healthcare Providers or due to potential drug interactions for which recommended monitoring would not be feasible.

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 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 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,
Eddie G M Power PhD MBA GFMD
Vice President, North America Medical Affairs