



## Pharmacovigilance Drug Safety Alert

### Additional Paxlovid dose packs authorized for patients with moderate renal impairment

April 15, 2022

The Food and Drug Administration (FDA) revised the Emergency Use Authorization (EUA) for the COVID-19 oral antiviral therapeutic Paxlovid to authorize an additional dose pack with appropriate dosing for patients with moderate renal impairment.

Paxlovid is approved 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.

eGFR (mL/min)	Dosing	Dose Pack Contents
≥60	300 mg nirmatrelvir with 100 mg ritonavir twice daily for 5 days	300 mg nirmatrelvir; 100 mg ritonavir Each carton contains 30 tablets divided in 5 daily-dose blister cards Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each)
≥30 to <60	150 mg nirmatrelvir and 100 mg ritonavir twice daily for 5 days	150 mg nirmatrelvir; 100 mg ritonavir Each carton contains 20 tablets divided in 5 daily-dose blister cards Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each)
<30	Not Recommended	

#### Recommendations for Healthcare Providers

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