



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.