Guidance for patients requiring dose adjustments due to renal impairment



In patients with moderate renal impairment, the dose of PAXLOVID should be reduced to:







Dose adjustment to avoid increased toxicity due to over-exposure (this dose adjustment has not been clinically tested).¹

Mild

 $(eGFR \ge 60 \text{ to } < 90 \text{ mL/min/1.73m}^2)$

Moderate (eGFR ≥30 to <60 mL/min/1.73m²)

Severe (eGFR <30 mL/min/1.73m²)

No dose adjustment required

Reduce dose to nirmatrelvir/ritonavir 150 mg/100 mg every 12 hours for 5 days

Contraindicated

The appropriate dose for patients with severe renal impairment has not yet been determined

Recommended actions for dispensing PAXLOVID

To dispense the recommended PAXLOVID dose (150 mg nirmatrelvir with 100 mg ritonavir) for patients with moderate renal impairment:

STEP ONE

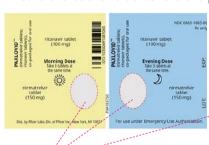
Remove one of the 150 mg nirmatrelvir tablets from the morning dose and remove one of the 150 mg nirmatrelvir tablets from the evening dose of the blister card (Figure 1). The nirmatrelvir tablets that are removed should be the ones closest to the middle of the blister pack.



Figure 1: Remove the nirmatrelvir tablets circled in red from the blister card

STEP TWO

Affix to the blister card one of the stickers provided to cover the empty blister cavities as shown in Figure 2. The exact placement of this sticker is important to cover the empty blister cavities from the tablets. Ensure the sticker also covers the pre-printed dosing instruction that is on the blister card.





Contact Pfizer to order more stickers for free (1800 PFIZER).

Figure 2: Placement of sticker over empty blister cavities and pre-printed dosing instruction after removal of nirmatrelvir tablets

STEP THREE

Repeat steps one and two for every blister card in the carton (each carton contains five blister cards for a full 5-day dosing regimen).

STEP FOUR

Affix one of the stickers provided to cover over the pre-printed dosing regimen on the carton as shown in Figure 3.





Figure 3: Placement of sticker over pre-printed dosing regimen on the carton

Discuss adjusted dose with the patient

Patients with moderate renal impairment should be alerted that only one tablet of nirmatrelvir with one tablet of ritonavir should be taken every 12 hours.

Provide Paxlovid Patient Leaflet to the patient

To support your discussion with your patients, please refer to the Paxlovid Patient Leaflet and go to the renal adjustment section for simple guidance for your patients that require dose adjustment of Paxlovid. It is also available by scanning the QR code here:



For more information about PAXLOVID visit www.paxlovid.com.au

PBS information: Authority Required (STREAMLINED).

Category: GENERAL – General Schedule (Code GE).

For verified SARS-CoV-2 infection. Treatment must be initiated within 5 days of symptom onset.

Refer to PBS Schedule for full authority information.

Warning: Nirmatrelvir with ritonavir has significant drug-drug interactions. Prescribers and dispensers should carefully review a patient's concomitant medications.

This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Alternatively, any adverse events which are experienced with PAXLOVID can be reported to Pfizer on 1800 675 229 or by email to AUS.AEReporting@pfizer.com



BEFORE PRESCRIBING, PLEASE REVIEW FULL PRODUCT INFORMATION AVAILABLE BY SCANNING THE QR CODE OR CALL 1800 675 229.



