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Pfizer New Zealand Limited

5th April 2022

Dear Healthcare Professional,

Supply of PAXLOVID™ (nirmatrelvir 150 mg/ritonavir 100 mg), film coated tablets, TT50-10969

The purpose of this letter is to make you aware of the dosing and dispensing requirements for patients with moderate renal impairment, the potential for drug-drug interactions associated with PAXLOVID (nirmatrelvir tablets; ritonavir tablets), and the international artwork used for packaging.

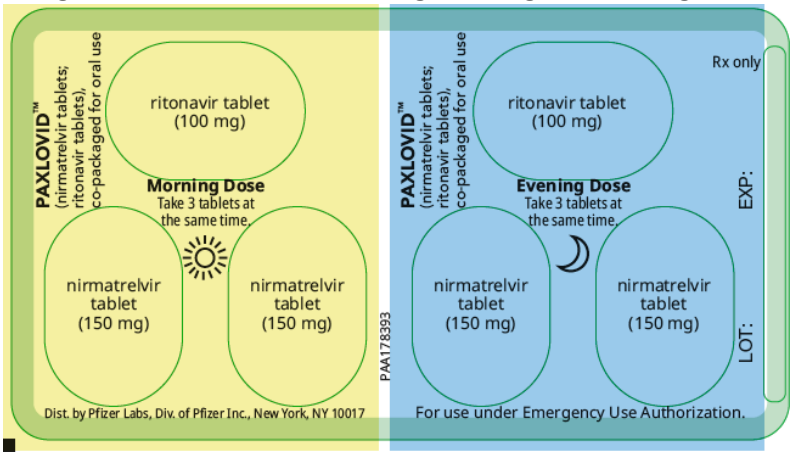
Pfizer New Zealand Limited has commenced supply of PAXLOVID (nirmatrelvir 150 mg/ritonavir 100 mg), film coated tablets. PAXLOVID has been granted consent for the following indication:

> Treatment of coronavirus disease 2019 (COVID-19) in adults 18 years of age and older, who do not require initiation of supplemental oxygen due to COVID-19 and are at increased risk of progression to hospitalisation or death.

Identification and artwork

PAXLOVID is supplied as a blister pack of 30 tablets in 5 blister cards. Each blister card contains 6 tablets, 4 nirmatrelvir tablets (150 mg each), 2 ritonavir tablets (100 mg each). The blister pack artwork (Figure 1) is designed to assist patients to take the correct dose (2 nirmatrelvir tablets and 1 ritonavir tablet) at the correct time (twice daily), see below:

Figure 1 - Blister card containing morning and evening dose



To assist with expedited supply of PAXLOVID to New Zealand, Medsafe has granted consent for the use of the international pack. Hence, the first shipments of PAXLOVID to New Zealand will be in cartons (Figure 2) and blisters (Figure 1) that look different to a New Zealand pack. The PAXLOVID tablets in the international artwork are identical in every way (formulation, method of manufacture, testing, appearance, etc.) to the ones granted consent for distribution by Medsafe for supply in New Zealand.

Figure 2 - Artwork for carton that will initially be supplied in New Zealand

The table below highlights the differences between the International PAXLOVID artwork and the NZ Pack.

	International Pack	**NZ Pack**
Carton		
Medicine classification and cautionary statements	Rx symbol is used	PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN
Sponsor details	Distributed by Pfizer Labs Division of Pfizer Inc. New York, NY 10017	Pfizer New Zealand Limited Auckland Medical Information: In New Zealand, go to www.pfizermedicalinformation.co.nz; or ph. 0800 736 363
Storage	Store at room temperature 20°C to 25 °C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)	Store below 25°C

Allergen statement	Not included	Contains sugars (as lactose)[1]
Other	For use under Emergency Use Authorisation. This is how the FDA have authorised PAXLOVID for use in the USA.	No statement is required. In New Zealand, Medsafe have granted PAXLOVID provisional consent for distribution under Section 23 of the medicines Act 1981.
Blister foil		
Sponsor details	Pfizer Labs, Div. of Pfizer Inc	Pfizer logo

[1] The level of lactose within this preparation should not routinely preclude the use of this medication in those with galactosaemia. See Section 4.4 Special warnings and precautions for use in the PAXLOVID Data Sheet.

Important information when prescribing and dispensing PAXLOVID to patients with renal impairment.

Each daily blister card contains a morning and evening dose, with each dose consisting of 300 mg nirmatrelvir (two oval, pink 150 mg tablets) and 100 mg ritonavir (one ovaloid, white 100 mg tablet) as shown in Figure 1 above, which is incongruent with the moderate renal impairment dose.

Each daily blister card contains more nirmatrelvir tablets than are needed for dosing in patients with moderate renal impairment. **It is critical that all prescriptions specify the numeric dose for each active ingredient within PAXLOVID and any tablets that are not required are discarded prior to dispensing and that this is discussed with the patient.**

The dosage for PAXLOVID in patients with renal impairment is as follows:

Renal Function (eGFR*)	**PAXLOVID Dose**
Normal renal function or mild renal impairment (*Greater than 60 mL/min*)	300 mg nirmatrelvir with 100 mg ritonavir, taken every 12 hours for 5 days
Moderate renal impairment (≥30 to <60 mL/min)	150 mg nirmatrelvir with 100 mg ritonavir, taken every 12 hours for 5 days
Severe renal impairment (<30 mL/min)	PAXLOVID is contraindicated.

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

Risk of Serious Adverse Reactions Due to Drug Interactions:

Use of PAXLOVID, a CYP3A inhibitor, in patients receiving some concomitant medications metabolised by CYP3A may increase the plasma concentrations of those concomitant medications, or may increase or decrease concentrations of PAXLOVID.

These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life-threatening, or fatal events from greater exposures of concomitant medications.
- Clinically significant adverse reactions from greater exposures of PAXLOVID.
- Loss of therapeutic effect of PAXLOVID and possible development of viral resistance.

Consider the potential for drug interactions prior to and during PAXLOVID therapy; review concomitant medications during PAXLOVID therapy and monitor for the adverse reactions associated with the concomitant medications. Tables 1 and 2 from the Data Sheet have been included below for your convenience. Please refer to the current New Zealand Data Sheet for the most up to date clinically significant drug interactions and contraindicated drugs.

Table 1: Medicinal products that are contraindicated for concomitant use with PAXLOVID and are associated with serious and/or life-threatening reactions

Medicinal product class	**Medicinal products within class**
Interactions that result in an increase or decrease in concentrations of concomitant medicine	
Antianginal	ranolazine
Antiarrhythmics	amiodarone, flecainide, propafenone
Antibiotic	fusidic acid
Anticancer	neratinib, venetoclax
Anti-gout	colchicine
Antipsychotics	clozapine
Ergot derivatives	ergometrine
Lipid-modifying agents HMG-CoA reductase inhibitors	simvastatin
Opioid analgesic	pethidine
PDE5 inhibitor	avanafil, sildenafil, vardenafil, tadalafil
Sedative/hypnotics	diazepam

Table 2: Medicinal products that are contraindicated for concomitant use with PAXLOVID and associated potential loss of virologic response and possible resistance.

Interactions that result in decrease in nirmatrelvir/ritonavir concentrations	
Anticancer	apalutamide
Anticonvulsant	carbamazepine[a], phenobarbital, phenytoin
Antimycobacterials	rifampicin
Herbal products	St. John's Wort (*hypericum perforatum*)

Prescribers and pharmacists should inform patients that PAXLOVID may interact with some drugs and is contraindicated for use with some drugs; therefore, patients should be advised to report to their healthcare provider the use of any prescription or non-prescription medication or herbal products.

PLEASE REVIEW THE CURRENT NEW ZEALAND DATA SHEET BEFORE PRESCRIBING OR DISPENSING.

The New Zealand Data Sheet and Consumer Medicine Information can be found at https://www.medsafe.govt.nz. The PAXLOVID New Zealand Data Sheet for Healthcare professionals is also available by scanning the QR Code below:

Adverse Event Reporting

Healthcare professionals are asked to report any suspected adverse events at https://nzphvc.otago.ac.nz/reporting/. Alternatively, any adverse events which are experienced with PAXLOVID can be reported to Pfizer on 0800 736 363 or by email to AUS.AEReporting@pfizer.com

Medical Enquiries

Please direct any medical enquiries to Medical Information via www.pfizermedicalinformation.co.nz or 0800 736 363.

Yours sincerely,

Pasquale Gargiulo
Associate Medical Director
Hospital Business Unit
Pfizer New Zealand