FACT SHEET FOR PATIENTS AND CAREGIVERS

INTERIM AUTHORIZATION OF PAXLOVID FOR THE TREATMENT OF CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with PAXLOVID for the treatment of mild-to-moderate coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This Fact Sheet contains information to help you understand the risks and benefits of taking the PAXLOVID you have received or may receive. This Fact Sheet also contains information about how to take PAXLOVID and how to report side effects or problems with the appearance or packaging of PAXLOVID.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild-to-severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

What is PAXLOVID?

PAXLOVID is used to treat mild-to-moderate COVID-19 in adults 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. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.

The Health Sciences Authority (HSA) has granted interim authorization of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, under the Pandemic Special Access Route (PSAR).

What does PAXLOVID contain?

PAXLOVID is nirmatrelvir tablets co-packaged with ritonavir tablets.

- Nirmatrelvir is supplied as oval, pink immediate-release, film-coated tablets debossed with “PFE” on one side and “3CL” on the other side. Each tablet contains 150 mg of nirmatrelvir with the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, and sodium stearyl fumarate. The following are the ingredients in the film coating: hydroxy propyl methylcellulose, iron oxide red, polyethylene glycol, and titanium dioxide.
- Ritonavir is supplied as white film-coated ovaloid tablets debossed with the "a"

logo and the code NK. Each tablet contains 100 mg of ritonavir with the following inactive ingredients: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, copovidone, sodium stearyl fumarate, and sorbitan monolaurate. Ingredients in the film coating: colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, polyethylene glycol 400, polyethylene glycol 3350, polysorbate 80, talc, and titanium dioxide.

What should I tell my healthcare provider before I take PAXLOVID?

Tell your healthcare provider if you:

- Have any allergies
- Have liver or kidney disease
- Are pregnant or plan to become pregnant
- Are breastfeeding a child
- Have any serious illnesses

Some medicines may interact with PAXLOVID and may cause serious side effects.

- **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Your healthcare provider can tell you if it is safe to take PAXLOVID with other medicines.
- You can ask your healthcare provider or pharmacist for a list of medicines that interact with PAXLOVID.
- Do not start taking a new medicine without telling your healthcare provider.

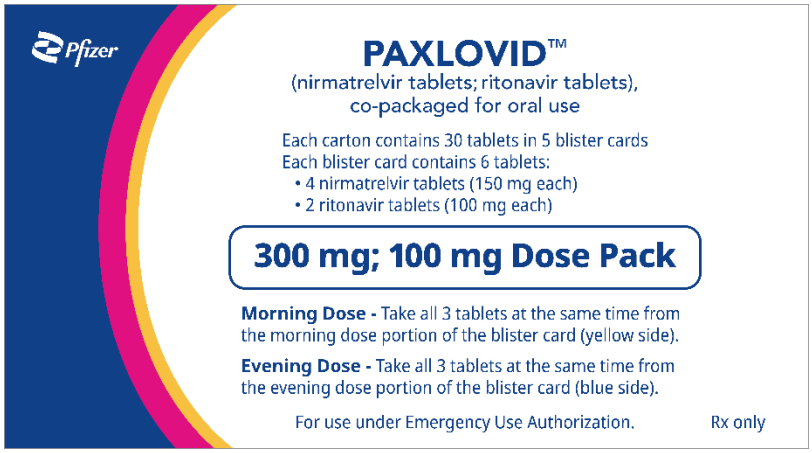
Tell your healthcare provider if you are taking combined hormonal contraceptive. PAXLOVID may affect how your birth control pills work. Females who are able to become pregnant should use another effective alternative form of contraception or an additional barrier method of contraception. Talk to your healthcare provider if you have any questions about contraceptive methods that might be right for you.

How do I take PAXLOVID?

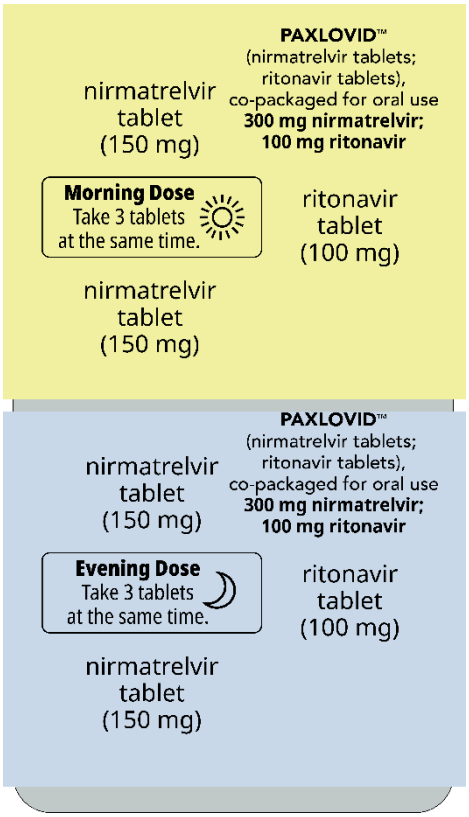
- PAXLOVID consists of 2 medicines: nirmatrelvir tablets and ritonavir tablets. The 2 medicines are taken together 2 times each day for 5 days.
    - Nirmatrelvir is an oval, pink tablet.
    - Ritonavir is a white tablet.
    - **If you have kidney disease, talk to your healthcare provider. You may need a different dose.**

Figure A

PAXLOVID 300 mg; 100 mg Dose Pack: each dose contains 3 tablets.



How to take PAXLOVID 300 mg; 100 mg Dose Pack



Morning Dose:
Take the 2 pink nirmatrelvir tablets and 1 white ritonavir tablet together at the same time each morning.

Evening Dose:
Take the 2 pink nirmatrelvir tablets and 1 white ritonavir tablet together at the same time each evening.

- Do not remove your PAXLOVID tablets from the blister card before you are ready to take your dose.
- Take your first dose of PAXLOVID in the Morning or Evening, depending on when you pick up your prescription, or as recommended by your healthcare provider.
- Swallow the tablets whole. Do not chew, break, or crush the tablets.
- Take PAXLOVID with or without food.
- Do not stop taking PAXLOVID without talking to your healthcare provider, even if you feel better.
- If you miss a dose of PAXLOVID within 8 hours of the time it is usually taken, take it as soon as you remember. If you miss a dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take 2 doses of PAXLOVID at the same time.
- If you take too much PAXLOVID, call your healthcare provider or go to the nearest hospital emergency room right away.
- If you are taking a ritonavir- or cobicistat-containing medicine to treat hepatitis C or Human Immunodeficiency Virus (HIV), you should continue to take your medicine as prescribed by your healthcare provider.

Talk to your healthcare provider if you do not feel better or if you feel worse after 5 days.

Who should generally not take PAXLOVID?

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID.
- You are taking any of the following medicines:
  - alfuzosin
  - amiodarone
  - apalutamide
  - carbamazepine
  - colchicine
  - dihydroergotamine
  - dronedarone
  - eletriptan
  - eplerenone
  - ergotamine
  - finerenone
  - flecainide
  - flibanserin
  - ivabradine
  - lomitapide
  - lovastatin
  - lumacaftor/ivacaftor
  - lurasidone
  - methylergonovine
  - midazolam (oral)
  - naloxegol
  - phenobarbital
  - phenytoin
  - pimozide
  - primidone
  - propafenone
  - quinidine
  - ranolazine
  - rifampin
  - St. John's Wort (*hypericum perforatum*)
  - sildenafil (Revatio®) for pulmonary arterial hypertension
  - silodosin
  - simvastatin
  - tolvaptan
  - triazolam
  - ubrogepant
  - voclosporin

Taking PAXLOVID with these medicines may cause serious or life-threatening side effects or affect how PAXLOVID works.

These are not the only medicines that may cause serious side effects if taken with PAXLOVID. PAXLOVID may increase or decrease the levels of multiple other

medicines. It is very important to tell your healthcare provider about all of the medicines you are taking because additional laboratory tests or changes in the dose of your other medicines may be necessary while you are taking PAXLOVID. Your healthcare provider may also tell you about specific symptoms to watch out for that may indicate that you need to stop or decrease the dose of some of your other medicines.

What are the important possible side effects of PAXLOVID?

Possible side effects of PAXLOVID are:

- **Allergic Reactions.** Allergic reactions, including severe allergic reactions (known as 'anaphylaxis'), can happen in people taking PAXLOVID, even after only 1 dose. Stop taking PAXLOVID and call your healthcare provider right away if you get any of the following symptoms of an allergic reaction:
    - hives
    - trouble swallowing or breathing
    - swelling of the mouth, lips, or face
    - throat tightness
    - hoarseness
    - skin rash
- **Liver Problems.** Tell your healthcare provider right away if you have any of these signs and symptoms of liver problems: loss of appetite, yellowing of your skin and the whites of eyes (jaundice), dark-colored urine, pale colored stools and itchy skin, stomach area (abdominal) pain.
- **Resistance to HIV Medicines.** If you have untreated HIV infection, PAXLOVID may lead to some HIV medicines not working as well in the future.
- **Other possible side effects include:**
    - altered sense of taste
    - diarrhea
    - high blood pressure
    - muscle aches
    - abdominal pain
    - nausea
    - feeling generally unwell

These are not all the possible side effects of PAXLOVID. Not many people have taken PAXLOVID. Serious and unexpected side effects may happen. PAXLOVID is still being studied, so it is possible that all of the risks are not known at this time.

What other treatment choices are there?
Like PAXLOVID, HSA may allow for the emergency use of other medicines to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you may be eligible.

It is your choice to be treated or not to be treated with PAXLOVID. Should you decide not to receive it, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is no experience treating pregnant women or breastfeeding mothers with PAXLOVID. If you are pregnant, discuss your options and specific situation with your healthcare provider.

It is recommended that you use effective barrier contraception or do not have sexual activity while taking PAXLOVID.

If you are breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects or problems with the appearance or packaging of PAXLOVID?
Contact your healthcare provider if you have any side effects that bother you or do not go away.

Report side effects or problems with the appearance or packaging of PAXLOVID (see Figure A) to **Pfizer Singapore** at the contact information provided below. Please include "PAXLOVID Interim Authorization" in the report.

Email	Fax number	Telephone number
SGP.AEReporting@pfizer.com	8001012817 (local toll free)	+65 6403 8888

How should I store PAXLOVID?
Store PAXLOVID tablets at or below 25°C.

How can I learn more about COVID-19?
- Ask your healthcare provider.
- Visit https://www.cdc.gov/COVID19.
- Contact your local or state public health department.

What is an Interim Authorization?
The HSA has made PAXLOVID available under an emergency access mechanism called the Interim Authorization. The Interim Authorization enables regulatory agilities in responding to an emergency that may pose serious threats to the public such as in the situation of a pandemic. Given the urgent public health need, HSA will prioritize the review of emergency therapeutic products to facilitate timely access while ensuring the scientific rigor of the assessment of their quality, safety and efficacy.

PAXLOVID has not undergone the same type of review as an HSA-approved medicine. In issuing an Interim Authorization, the HSA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for treating or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential

benefits of the product, when used to treat or prevent such disease or condition, outweigh the known and potential risks of such product; and that there is on-going quality, safety and efficacy data generated to support the eventual transition of the Interim Authorization to product registration.

Additional Information
For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.COVID19oralRx.com	+65 6403 8888

Should you have any medical information enquires, you may submit it at https://pmiform.com/HCP/SG.

Alternatively, you may send them to MedicalInformationSingapore@pfizer.com.

Product Registrant
Pfizer Private Limited
80 Pasir Panjang Road, #16-81/82
Mapletree Business City, Singapore 117372

Reference label: US LAB-1494-6.0, LAB-1494-7.0 and LAB-1494-8.0

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