CONDITIONS

Nirmatrelvir and Ritonavir (PAXLOVID)
TREATMENT OF COVID-19 INFECTION

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe nirmatrelvir and ritonavir (PAXLOVID).

- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized PAXLOVID Patient Intake Form (pg. 2-3)
  - Utilize the standardized PAXLOVID Assessment and Treatment Care Pathway (pg. 6-9)
  - Utilize the standardized PAXLOVID Provider Notification (pg. 20)

  PHARMACIST TRAINING/EDUCATION:
  - Pharmacist is familiar with how to access patient laboratory data to assess renal and hepatic function.
  - Review PAXLOVID resources for healthcare providers, available at:
    - https://www.paxlovidhcp.com/
    - FDA: PAXLOVID Patient Eligibility Screening Checklist Tool for Prescribers
  - A minimum of 1 hour of training **is recommended**
    - CDC 6/16/2022 Webinar: What Clinicians Need to Know About Available Therapeutic Options for COVID-19
    - CDC 1/12/2022 Webinar: What Clinicians Need to Know About the New Oral Antiviral Medications for COVID-19

Nirmatrelvir and Ritonavir (PAXLOVID) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

If you have any of the following, please go directly to the emergency room or have someone call 911.

□ New confusion □ Difficulty breathing □ Pain or pressure in the chest
□ Cannot stay awake □ Gray or blue-colored skin, lips, or nail beds □ Fast heart rate or palpitations
□ If you are on oxygen and have greater oxygen needs

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____
Legal Name_____ Name _____
Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____
Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Theirs, Ze/Hir/Hirs, Other_____Height_____Weight____
Street Address _____
Phone ( ) _____ Email Address _____
Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____
Do you have health insurance? □ Yes □ No Insurance Provider Name _____
Any allergies to medications? □ Yes □ No If yes, please list _____
Which of the following best describes your racial or ethnic identity? Please check **ALL** that apply.
□ Black/African American □ Hispanic or Latino/a/x □ American Indian or Alaska Native □ Asian □ Other
□ Native Hawaiian/Pacific Islander □ Middle Eastern/North African □ White □ Not specified
Are you houseless, or live in a shelter, encampment, or transitional housing? □ Yes □ No

Background Information:

1.	Have you had a positive COVID-19 (SARS-CoV-2) antigen test within the past 5 days? If yes, please indicate the date of the positive test ___/___/_____.	□ Yes □ No
2.	Have you experienced any of the following symptoms? If yes, select all that apply: □ Fever □ Chills □ Cough □ Fatigue □ Headache □ Sore throat or Laryngitis □ Difficulty breathing □ Muscle or body aches □ Loss of taste or smell □ Congestion/head cold □ Runny nose □ Nausea or Vomiting □ Diarrhea □ Loss of appetite □ Light sensitivity If yes, did the symptoms start in the past 5 days?	□ Yes □ No □ Yes □ N/A
3.	Do you have or have you had any of the following that would qualify you for COVID-19 treatment? Please ask the Pharmacist if you have any questions about this list.	
	A. Age 50 years or older	□ Yes □ No
	B. Asthma	□ Yes □ No
	C. Cancer	□ Yes □ No
	D. Cystic fibrosis	□ Yes □ No
	E. Dementia	□ Yes □ No
	F. Diabetes	□ Yes □ No
	G. Disability (e.g., mental, physicial, emotional)	□ Yes □ No
	H. Heart condition	□ Yes □ No
	I. HIV infection	□ Yes □ No
	J. Immune system problems or medications affecting the immune system	□ Yes □ No
	K. Kidney disease	□ Yes □ No
	a. If yes, are you currently on dialysis?	□ Yes □ No
	L. Liver disease	□ Yes □ No
	M. Lung disease or blood clot in the lung	□ Yes □ No
	N. Mental health condition	□ Yes □ No
	O. Unvaccinated or not up to date on COVID-19 vaccinations	□ Yes □ No
	P. Overweight or obese	□ Yes □ No
	Q. Physically inactive	□ Yes □ No
	R. Pregnancy or recent pregnancy	□ Yes □ No

Nirmatrelvir and Ritonavir (PAXLOVID) Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

	S. Sickle cell disease or thalassemia……	□ Yes □ No
	T. Smoking, current or former……	□ Yes □ No
	U. Transplant of organ or bone marrow……..	□ Yes □ No
	V. Stroke or brain bleed……	□ Yes □ No
	W. Problematic drug or alcohol use……..	□ Yes □ No
	X. Tuberculosis……	□ Yes □ No
	Y. Other: _____	□ Yes □ No
4.	Have you had bloodwork of kidney and liver function that is less than 12 months old? If yes, can you provide it to the Pharmacist now?	□ Yes □ No □ Yes □ No
5.	Do you have any known medication allergies? If yes, list them here:	□ Yes □ No
6.	Do you take any medicines, including herbs or supplements? If yes, list them here:	□ Yes □ No (notify Pharmacist if more space needed)
7.	Do you take any medicines that you do not remember the name of?	□ Yes □ No
8.	Please write the names of all pharmacies you have filled prescriptions with in the last 90 days: Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____ Pharmacy (location):_____	

Signature_____ Date ____/_____/_____

TO BE COMPLETED BY PHARMACIST:

1. Weight _____ lbs.
   a. If applicable to verify overweight/obese status as only risk factor: Height __ ft. ___ in., BMI _____
2. Renal function:
   a. Provider verified eGFR is ≥60 mL/min *or* ≥30 to <60 mL/min *or* <30 mL/min (circle one).
      Provider name (phone):_____ **-or-**
   b. SCr:_____ mg/dL (date of lab:___/___/___). eGFR using CKD-EPI formula:_____ mL/min
3. Hepatic function:
   a. Provider-verified patient has: No Cirrhosis *or* Child-Pugh Class A *or* Class B *or* Class C (circle one)
      Provider name/phone:_____ **-or-**
   b. Total Bilirubin_____ mg/dL (date of lab:___/___/___), Albumin:_____ g/dL (date of lab:___/___/___),
      INR or Prothrombin Time (sec):_____ (date of lab:___/___/___).
      Child-Pugh score:_____ (6 points added for missing ascites and encephalopathy information)
      Estimated Child-Pugh: Class A: 5-6 points *or* Class B: 7-9 points *or* Class C: 10-15 points (circle one)

IF PAXLOVID WAS PRESCRIBED, COMPLETE THE FOLLOWING:

1. EUA Fact Sheet for Patients, Parents and Caregivers was provided: Version Date____/_____
2. Dose (check one):
   □ Nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days
   □ Nirmatrelvir 150 mg (one 150 mg tablet) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days
3. Healthcare Provider (if known) contacted/notified of therapy: □ Yes Date ____/_____/_____ □ Not Applicable

RPH Signature_____Date ____/_____/_____

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

REALD Data Collection Form

Date _____/_____/_____ Date of Birth _____/_____/_____ Age_____

Legal Name_____ Preferred Name _____

1. Which of the following describes your **Racial or Ethnic identity**? Please check **ALL** that apply.

Hispanic and Latino/a/x
□ Central American
□ Mexican
□ South American
□ Other Hispanic or Latino/a/x

Native Hawaiian and Pacific Islander
□ CHamoru (Chamorro)
□ Marshallese
□ Communities of the Micronesian Region
□ Native Hawaiian
□ Samoan
□ Other Pacific Islander

White
□ Eastern European
□ Slavic
□ Western European
□ Other White

American Indian and Alaska Native
□ American Indian
□ Alaska Native
□ Canadian Inuit, Metis, or First Nation
□ Indigenous Mexican, Central American, or South American

Black and African American
□ African American
□ Afro-Caribbean
□ Ethiopian
□ Somali
□ Other African (Black)
□ Other Black

Middle Eastern/North African
□ Middle Eastern
□ North African

Asian
□ Asian Indian
□ Cambodian
□ Chinese
□ Communities of Myanmar
□ Filipino/a
□ Hmong
□ Japanese
□ Korean
□ Laotian
□ South Asian
□ Vietnamese
□ Other Asian

Other Categories
□ Other (please list)
_____
□ Don't know
□ Don't want to answer

2. If you checked **more than one** category above, is there **<u>one</u>** you think of as your **primary** racial or ethnic identity?
   □ Yes. Please circle your primary racial or ethnic identity above.
   □ I do not have just one primary racial or ethnic identity.
   □ No. I identify as Biracial or Multiracial.
   □ N/A. I only checked one category above.
   □ Don't know
   □ Don't want to answer

Language (*Interpreters are available at no charge*)

3. What language or languages do you **use at home**? _____
   → Skip to question 9 if you indicated English only

4. In what language do you want us to communicate in **person, on the phone, or virtually** with you?

5. In what language do you want us to **write** to you? _____

6. Do you need or want an **interpreter** for us to communicate with you?
   □ Yes □ No □ Don't know □ Don't want to answer

7. If you need or want an interpreter, what type of interpreter is preferred?
□ Spanish language interpreter □ Deaf Interpreter for DeafBlind, additional barriers, or both
□ American Sign Language interpreter □ Contact sign language (PSE) interpreter
□ Other (**please list**): _____

→ Skip to question 9 if you do not use a language other than English or sign language

8. How well do you speak English?
□ Very Well □ Well □ Not Well □ Not at all □ Don't know □ Don't want to answer

	Disability Your answers will help us find health and service differences among people with and without functional difficulties. Your answers are confidential.	Yes	***If yes**, at what age did this condition begin?	No	Don't know	Don't want to answer	Don't know what this question is asking
9.	Are you deaf or do you have serious difficulty hearing?						
10.	Are you blind or do you have serious difficulty seeing, even when wearing glasses?						
11.	Do you have serious difficulty walking or climbing stairs?						
12.	Because of a physical, mental or emotional condition, do you have serious difficulty concentrating, remembering or making decisions?						
13.	Do you have difficulty dressing or bathing?						
14.	Do you have serious difficulty learning how to do things most people your age can learn?						
15.	Using your usual (customary) language, do you have serious difficulty communicating (for example understanding or being understood by others)?						
16.	Because of a physical, mental or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping?						
17.	Do you have serious difficulty with the following: mood, intense feelings, controlling your behavior, or experiencing delusions or hallucinations?						

All health care providers must begin collecting and reporting REALD data in accordance with current REALD standards and Oregon Disease Reporting rules starting October 1, 2021.

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

1) Assessment Screen (Self-screening Patient Intake Form, REALD demographics and pharmacist assessment)

a. Age < 12 years → **Refer to healthcare provider**
b. Weight < 88 lbs (40 kg) → **Refer to healthcare provider**
c. Clinical Factors listed below: → **Refer immediately to local Emergency Department or call 911**
   If the Pharmacist observes or the patient reports:
   □ New confusion □ Difficulty breathing □ Cannot stay awake
   □ Pain or pressure in the chest □ Gray or blue-colored skin, lips, or nail beds
   □ Fast heart rate or palpitations □ If patient is on oxygen and has greater oxygen needs

If referral criteria not met, *proceed to Step 2*.

2) Treatment Screen (Self-screening Patient Intake Form #1-2)

a. Positive SARS-CoV-2 molecular or antigen test within past 5 days associated with current symptoms?

   NOTE: Test results that are indeterminate or inconclusive results can suggest the presence of SARS-CoV2 in quantities insufficient for the molecular or antigen test to be positive. It is recommended to collect a new specimen and retest. If the results are still indeterminate or inconclusive, the patient should be referred to their healthcare provider for further evaluation.

b. Onset of mild to moderate COVID-19 symptoms within past 5 days?

   NOTE: fever or chills; cough; shortness of breath or difficulty breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea, vomiting; or diarrhea

If YES to *BOTH* Steps 2a **AND** 2b, *proceed to Step 3*.

3) Risk of Progression to Severe COVID-19 Screen (Self-screening Patient Intake Form #3, REALD demographics)

a. Did the patient attest to at least one risk factor in #3 on the Self-screening Patient Intake Form, which places an individual at high risk of progression to severe COVID-19?

   NOTE: Pharmacist must obtain or calculate BMI to verify overweight/obese status if #3.P. is the *only* risk factor checked "Yes" on #3 of the Self-screening Patient Intake Form. A BMI ≥25 is a risk factor.

b. Does the patient identify as Black, African American, Hispanic, Latino/a/x, American Indian/Alaska Native, Asian, Asian American, or Pacific Islander, which places an individual at high risk of progression to severe COVID-19?

   NOTE: Patients of color or from tribal communities are most harmed by health inequities and the risk of hospitalization and death for these groups is greater than that of white patients. These patients may face higher risk than white patients due to longstanding societal injustices including racism, discrimination, colonization, etc., which have and continue to negatively affect health outcomes. For this

reason, people who identify as Black/African American, Hispanic, Latino/a/x, American Indian/Alaska Native, Asian/Asian American or Pacific Islander are eligible for PAXLOVID under this protocol.

c. Is the patient houseless or live in a shelter, encampment or transitional housing, which places an individual at high risk of progression to severe COVID-19?

NOTE: There is increased transmission of virus in indoor and outdoor congregate settings that do not provide protection from the environment, adequate access to hygiene and sanitation facilities, or connection to services and health care. These settings include those where people who are houseless, are sleeping outdoors or in encampments. For this reason, people who are houseless are eligible for PAXLOVID under this protocol.

If YES to *EITHER* Step 3a, 3b, **OR** 3c, *proceed to Step 4*; otherwise, *PAXLOVID is not indicated at this time → Refer as outlined in EUA.*

4) Renal Function Assessment Screen

a. Is the patient currently on dialysis as reported on the Self-Screening Patient Intake Form Question #3.K.a.?

b. Did the pharmacist verify an eGFR ≥30 mL/min after consultation with a healthcare provider who is in an established patient-provider relationship with the individual patient?

c. Did the pharmacist obtain a SCr level that is **less than 12 months** old and calculate an eGFR ≥30 mL/min using an online calculator based on the 2021 CKD-EPI equation?

Note: Patient reporting of renal function is not adequate for utilization of this protocol.

If YES to Step 4a, PAXLOVID is contraindicated. → *Refer as outlined in EUA.*
If YES to *EITHER* Step 4b **OR** 4c, *proceed to Step 5; otherwise*, → *Refer as outlined in EUA.*

5) Hepatic Function Assessment Screen

a. Did the pharmacist verify the patient does not have Child-Pugh Class C liver disease (severe, decompensated) after consultation with a healthcare provider who is in an established patient-provider relationship with the individual patient?

b. Did the pharmacist obtain a total bilirubin, albumin and INR/prothrombin time that is less than 12 months old and estimate the Child-Pugh score to be <10 points (No liver cirrhosis, or Child-Pugh Class A or B) using an online calculator?

If provider cannot be consulted to verify hepatic function, pharmacist may calculate the Child-Pugh score using 3 points for missing ascites data and 3 points for missing encephalopathy data (adds 3 points for each missing data) for most conservative estimate.

Note: Patient reporting of liver function is not adequate for utilization of this protocol.

If YES to *EITHER* Step 5a **OR** 5b, *proceed to Step* 6; otherwise, → *Refer as outlined in EUA.*

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

6) Allergy Screen (Self-screening Patient Intake Form #5)

Does the patient have a known allergy/hypersensitivity to any ingredient of PAXLOVID?

If NO known allergy, *proceed to Step 7*; otherwise, PAXLOVID is contraindicated → *Refer as outlined in EUA.*

7) Assessment of Drug-Drug Interactions (Self-screening Patient Intake Form #6-8)

a. Did the pharmacist obtain a comprehensive list of current medications and supplements (prescribed and non-prescribed):
   i. Through access to health records or pharmacy records less than 12 months old **-or-**
   ii. In consultation with a healthcare provider in an established patient-provider relationship with the patient **-or-**
   iii. Through patient reporting

b. After review of the medications, did the pharmacist identify potential serious drug interactions with PAXLOVID? Tool to assess drug interactions include:
   - Databases like Micromedex, Lexicomp or the drug interaction program provided by the pharmacy and routinely used by the pharmacist
   - The Fact Sheet for Healthcare Providers (Section 7)
   - The FDA PAXLOVID Eligibility Screening Checklist Tool
   - The University of Liverpool COVID-19 Drug Interactions tool

If YES to Step 7a **AND** *NO* to Step 7b, *proceed to Step 8; otherwise,* → *Refer as outlined in EUA.*

8) Document the Patient Education

Document that you communicated to your patient or parent/caregiver, as age appropriate, information consistent with:

a. The "Fact Sheet for Patients, Parents, and Caregivers - Emergency Use Authorization (EUA) of PAXLOVID" and provided a copy of this Fact Sheet to the patient or parent/caregiver prior to the patient receiving PAXLOVID
b. Patient Counseling Information outlined in Section 17 of the Fact Sheet for Healthcare Providers.
c. Patients treated with PAXLOVID should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

9) Prescribe PAXLOVID

a. If eGFR ≥60 mL/min: nirmatrelvir 300 mg (two 150 mg tablets) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days, or
b. If eGFR ≥30 to <60 mL/min: nirmatrelvir 150 mg (one 150 mg tablet) and ritonavir 100 mg (one 100 mg tablet) twice daily for 5 days.

10) Notify primary care provider (if known) within 5 days of receipt of therapy

Standardized Assessment and Treatment Care Pathway
Nirmatrelvir and Ritonavir (PAXLOVID)

Adverse Reactions and Medication Errors Reporting Requirements:

Required reporting for serious adverse events and medication errors using FDA form 3500 as described in section 6.4 of EUA within 7 calendar days from the pharmacist's awareness of the event.

An Oregon-licensed pharmacist must adhere to the most current EUA when prescribing PAXLOVID.

COVID Antiviral (Paxlovid™) Prescription

Optional-May be used by pharmacy if desired

Patient Name:	Date of birth:
Address:	
City/State/Zip Code:	Phone number:

☐ Verified DOB with valid photo ID

Rx

☐ Drug: Paxlovid- Nirmatrelvir 300mg/ Ritonavir 100 mg

- Sig: Take two tablets of nirmatrelvir 150 mg tablets (300mg) and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #30
- Refills: none

☐ Drug: Paxlovid Renal- Nirmatrelvir 150mg/ Ritonavir 100 mg

- Sig: Take one tablet of nirmatrelvir 150 mg tablets and one tablet of ritonavir 100 mg twice daily for 5 days
- Quantity: #20
- Refills: none

Written Date: _____

Prescriber Name: _____Prescriber Signature: _____

Pharmacy Address: _____ Pharmacy Phone: _____

-or-

☐ Patient Referred

Notes:_____
_____
_____
_____

FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF PAXLOVID FOR 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.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make PAXLOVID available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). PAXLOVID is not an FDA approved medicine in the United States. Read this Fact Sheet for information about PAXLOVID. Talk to your healthcare provider about your options or if you have any questions. It is your choice to take 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 an investigational medicine used to treat mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] 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. PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.

The FDA has authorized the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] 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 an EUA.

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.

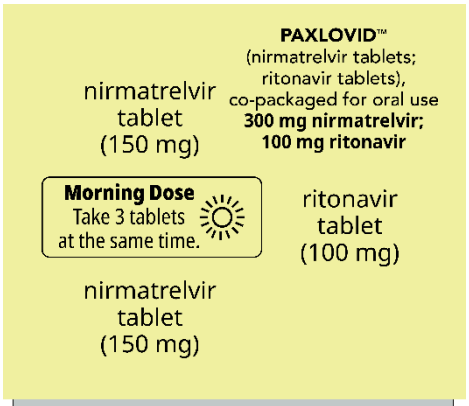
How do I take PAXLOVID?

- **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 or off-white tablet.
- PAXLOVID is available in 2 Dose Packs (see **Figures A and B** below). Your healthcare provider will prescribe the PAXLOVID Dose Pack that is right for you.
- **If you have kidney disease, your healthcare provider may prescribe a lower dose (see Figure B). Talk to your healthcare provider to make sure you receive the correct Dose Pack.**

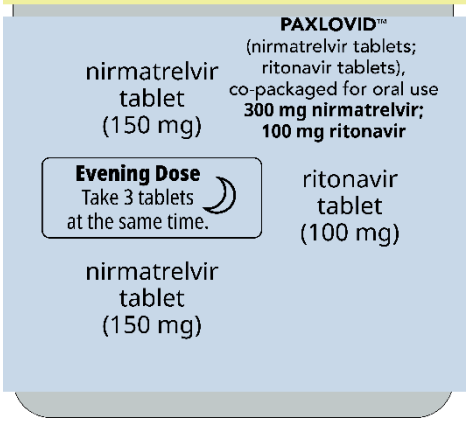
Figure A

If you have a PAXLOVID 300 mg; 100 mg **Dose Pack**: each dose contains 3 tablets.

How to take PAXLOVID 300 mg; 100 mg Dose Pack



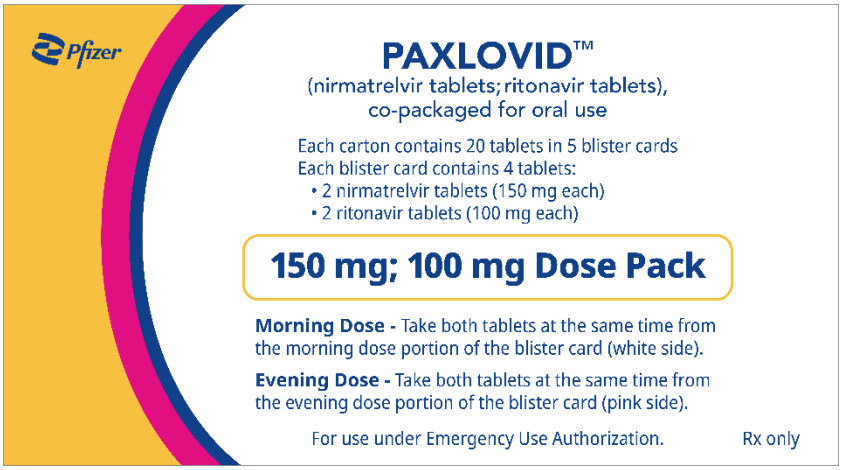
Morning Dose:
Take the 2 pink nirmatrelvir tablets and
1 white to off-white ritonavir tablet together
at the same time each morning.



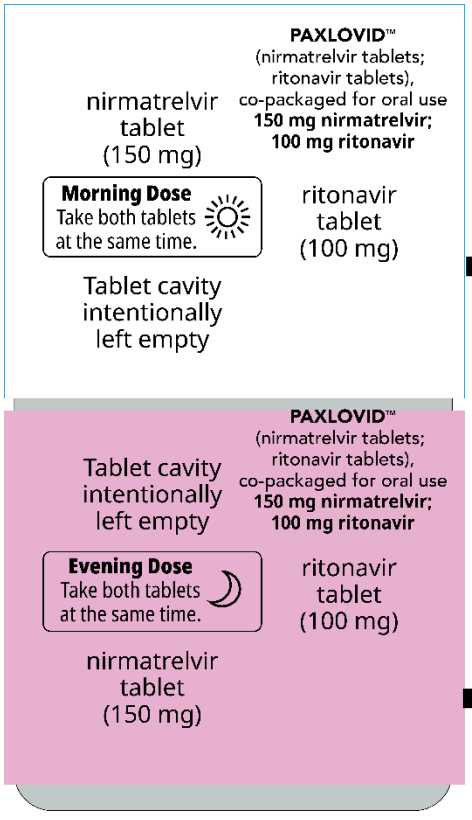
Evening Dose:
Take the 2 pink nirmatrelvir tablets and
1 white to off-white ritonavir tablet together
at the same time each evening.

Figure B

If you have a PAXLOVID 150 mg; 100 mg **Dose Pack**: each dose contains 2 tablets.



How to take PAXLOVID 150 mg; 100 mg Dose Pack



Morning Dose:
Take the 1 pink nirmatrelvir tablet and
1 white to off-white ritonavir tablet together
at the same time each morning.

Evening Dose:
Take the 1 pink nirmatrelvir tablet and
1 white to off-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?
Veklury (remdesivir) is FDA-approved for the treatment of mild-to-moderate COVID-19 in certain adults and children. Talk with your healthcare provider to see if Veklury is appropriate for you.

Like PAXLOVID, FDA may also allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for

information on the emergency use of other medicines that are authorized by FDA 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 or for your child 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. For a mother and unborn baby, the benefit of taking PAXLOVID may be greater than the risk from the treatment. 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 Figures A and B above for examples of PAXLOVID Dose Packs) to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

How should I store PAXLOVID?
Store PAXLOVID tablets at room temperature, between 68°F to 77°F (20°C to 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 Emergency Use Authorization (EUA)?
The United States FDA has made PAXLOVID available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to

justify the emergency use of drugs and biological products during the COVID-19 pandemic.

PAXLOVID for the treatment of mild-to-moderate COVID-19 in adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] 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, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, 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 diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for PAXLOVID is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless terminated or revoked (after which the products may no longer be used under the EUA).

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

Website	Telephone number
www.COVID19oralRx.com	1-877-219-7225 (1-877-C19-PACK)

You can also go to www.pfizermedinfo.com or call 1-800-438-1985 for more information.

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Provider Notification
COVID Antiviral (Paxlovid™)

Pharmacy Name:_____ Pharmacist Name: _____

Pharmacy Address:_____

Pharmacy Phone: _____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) was:

☐ **Prescribed** (Paxlovid™) at our Pharmacy noted above on ___/___/_____. The prescription issued and dispensed consisted of:

- Paxlovid- Nirmatrelvir 300mg/ Ritonavir 100 mg
  - Sig: Take two tablets of nirmatrelvir 150 mg tablets (300mg) and one tablet of ritonavir 100 mg twice daily for 5 days, #30, no refills
- Paxlovid Renal- Nirmatrelvir 150mg/ Ritonavir 100 mg
  - Sig: Take one tablet of nirmatrelvir 150 mg tablets and one tablet of ritonavir 100 mg twice daily for 5 days, #20, no refills

Your patient was:

- Provided with the FDA EUA Paxlovid™ Fact Sheet for Patients, Parents, & Caregivers https://www.fda.gov/media/155051/download
- Informed that an office visit with you or another provider on your team is recommended after taking a COVID antiviral.
- For treatment or post-exposure prevention of COVID-19, the patient was also advised that they should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect "high touch" surfaces, and frequent handwashing) according to CDC guidelines.

If you have further questions: Please contact the prescribing pharmacy or call the Pfizer Medical Information Department at 1-800-438-1985. Clinicians can review the NIH COVID-19 Treatment Guidelines as well as the FDA EUA for the therapy.

- NIH COVID-19 Treatment Guidelines: https://www.covid19treatmentguidelines.nih.gov/management/clinical-management-of-adults/nonhospitalized-adults--therapeutic-management/
- FDA EUA Paxlovid™ Fact Sheet for Healthcare Providers https://www.fda.gov/media/155050/download

Attention Pharmacy: This is a template document. Please feel free to customize it to your pharmacy, however you must retain all elements set forth by this template. The information may be transmitted electronically.