

# RENAL

## RENAL Dosing Instruction Sheet



There are 2 Dosing Guides for patients' use: the Standard Dosing Guide and the Renal Dosing Guide.

This is the **RENAL** Dosing Guide.

- Ensure patients with moderate renal impairment (eGFR  $\geq 30$  to  $< 60$  mL/min) are only receiving the **RENAL** Dosing Guide. **DO NOT distribute both guides**
- PAXLOVID is not recommended in patients with severe renal impairment (eGFR  $< 30$  mL/min)
- Confirm that the **RENAL** Dosing Guide matches the patient's prescription before giving them this sheet
- Counsel your patient to use the pictures on the Dosing Guide to help them take the correct dose

# How to take PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets)

This dosing guide is intended for people with **moderate kidney disease** who have been prescribed PAXLOVID by their healthcare provider.

PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 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.

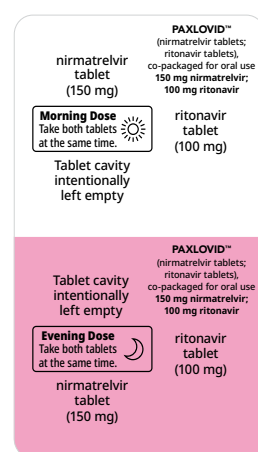
The emergency use of PAXLOVID is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

- PAXLOVID consists of 2 medicines: nirmatrelvir (pink) tablets and ritonavir (white to off-white) tablets. The 2 medicines are taken together 2 times each day for 5 days
- PAXLOVID is available in 2 Dose Packs. 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. Talk to your healthcare provider to make sure you receive the correct Dose Pack**
- Do not remove your PAXLOVID tablets from the blister card before you are ready to take your dose
- **Review the instructions on the blister card label carefully before taking 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

## Moderate Renal Impairment Dose: If you have a yellow PAXLOVID 150 mg; 100 mg Dose Pack, each dose contains 2 tablets



## How to take PAXLOVID 150 mg; 100 mg Dose Pack



### Morning Dose:

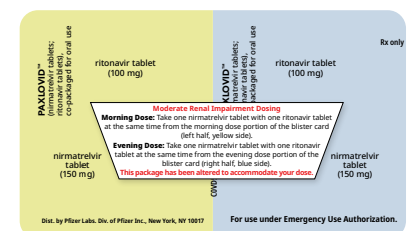
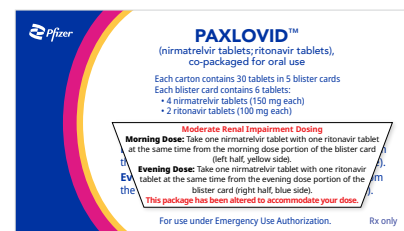
Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together at the same time each morning.

### Evening Dose:

Take the 1 pink nirmatrelvir tablet and 1 white to off-white ritonavir tablet together at the same time each evening.

Instead of receiving the yellow Dose Pack shown above, you may receive a blue Dose Pack with blister cards that have been adjusted by your pharmacist.

- If you receive this adjusted blister card, tablets will have been removed by your pharmacist
- A sticker with instructions will be placed on the carton and over the empty blister cavities



For the most up-to-date information, including Important Safety Information, please visit [paxlovid.com](http://paxlovid.com) or **scan the QR code**.



For the most up-to-date Patients, Parents, and Caregivers Fact Sheet, please visit [paxlovid.com](http://paxlovid.com) or **scan the QR code**.

Please see additional Important Safety Information throughout this resource and the Fact Sheet for Patients, Parents, and Caregivers at [www.paxlovid.com](http://www.paxlovid.com).

## AUTHORIZED USE

The FDA has authorized the emergency use of PAXLOVID, an investigational medicine, 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.

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.

## IMPORTANT SAFETY INFORMATION

**Before taking PAXLOVID, tell your healthcare provider if you:**

- Have any allergies
- Are pregnant or plan to become pregnant
- Have liver or kidney disease
- 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.

Please see additional Important Safety Information on next page.

## IMPORTANT SAFETY INFORMATION (CONT'D)

**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 TO TAKE PAXLOVID

- **PAXLOVID consists of 2 medicines: nirmatrelvir and ritonavir. 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. 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. Talk to your healthcare provider to make sure you receive the correct Dose Pack.**
- 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 the dose by more than 8 hours, skip the missed dose and take the next dose at your regular time. Do not take morning and evening 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.

### 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 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.

### 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
  - swelling of the mouth, lips, or face
  - hoarseness
  - trouble swallowing or breathing
  - throat tightness
  - 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, or 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
  - muscle aches
  - nausea
  - diarrhea
  - abdominal pain
  - feeling generally unwell
  - high blood pressure

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 risks are not known at this time.

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. It is recommended that you use effective barrier contraception or do not have sexual activity while taking PAXLOVID. **If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.**

**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 to **FDA MedWatch** at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088, or you can report side effects to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com), by fax at 1-866-635-8337, or by calling 1-800-438-1985.

Please see **Fact Sheet for Healthcare Providers** and **Fact Sheet for Patients, Parents, and Caregivers** at [paxlovid.com](http://paxlovid.com).

