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 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 for the treatment of mild-to-moderate COVID-19 in children 12 years of age and older weighing at least 88 pounds (40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). 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 a medicine that is available under EUA for the treatment of mild-to-moderate COVID-19 in children 12 years of age and older weighing at least 88 pounds (40 kg) who are at high risk for progression to severe COVID-19, including hospitalization or death.

PAXLOVID is FDA-approved for the treatment of COVID-19 in certain adults (see section **What other treatment choices are there?**).

PAXLOVID is not FDA-approved or available under EUA for use in children younger than 12 years of age or weighing less than 88 pounds (40 kg).
There is limited information about the safety and effectiveness of using PAXLOVID to treat children younger than 12 years of age or weighing less than 88 pounds (40 kg) with mild-to-moderate COVID-19.

What is the most important information I should know about PAXLOVID?
PAXLOVID can interact with other medicines causing severe or life-threatening side effects or death. It is important to know the medicines that should not be taken with PAXLOVID.

Do not take PAXLOVID if:

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

These are not the only medicines that may cause serious or life-threatening 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 during treatment with 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.

- you are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID. See the end of this leaflet for a complete list of ingredients in PAXLOVID. See **"What are the important possible side effects of PAXLOVID?"** for signs and symptoms of allergic reactions.

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

Tell your healthcare provider if you:

- have kidney problems. You may need a different dose or dosing schedule of PAXLOVID.
- have liver problems, including hepatitis.
- have Human Immunodeficiency Virus 1 (HIV-1) infection. PAXLOVID may lead to some HIV-1 medicines not working as well in the future.

- are pregnant or plan to become pregnant. It is not known if PAXLOVID can harm your unborn baby. Tell your healthcare provider right away if you are or if you become pregnant.
- are breastfeeding or plan to breastfeed. PAXLOVID can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with PAXLOVID.

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

How do I take PAXLOVID?

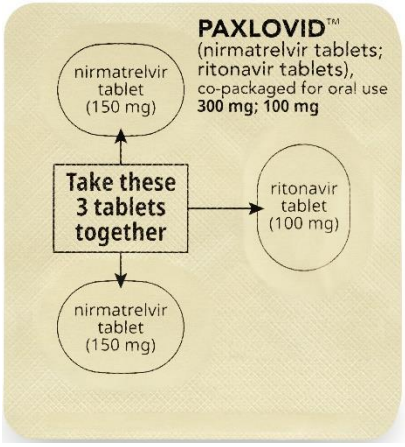
- Take PAXLOVID exactly as your healthcare provider tells you to take it.
- **PAXLOVID consists of 2 medicines: nirmatrelvir tablets and ritonavir tablets. The 2 medicines are taken together for 5 days.**
    - Nirmatrelvir is an oval, pink tablet.
    - Ritonavir is a white or off-white tablet.
- PAXLOVID is available in 3 Dose Packs (see **Figures A, B, and C** below). Your healthcare provider will prescribe the PAXLOVID Dose Pack that is right for you. Follow the instruction for the Dose Pack you receive.
- **If you have kidney disease, your healthcare provider may prescribe a lower dose (see Figures B and C). Talk to your healthcare provider to make sure you receive the correct Dose Pack.**

Figure A

If you are prescribed PAXLOVID 300 mg; 100 mg Dose Pack
Each dose contains 3 tablets taken together twice daily

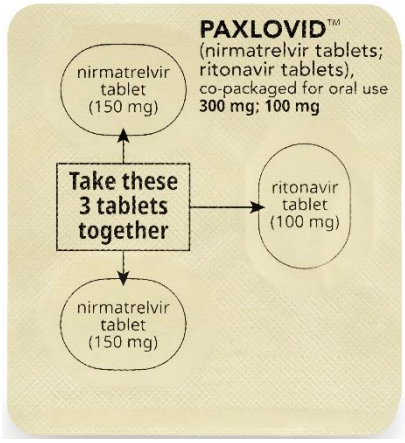


How to take PAXLOVID 300 mg; 100 mg Dose Pack



<u>Morning Dose:</u>
Take the 2 pink nirmatrelvir tablets and
1 white to off-white ritonavir tablet together.





<u>Bedtime Dose:</u>
Take the 2 pink nirmatrelvir tablets and
1 white to off-white ritonavir tablet together.



Figure B

If you are prescribed PAXLOVID 150 mg; 100 mg Dose Pack
Each dose contains 2 tablets taken together twice daily



How to take PAXLOVID 150 mg; 100 mg Dose Pack



<u>Morning Dose:</u>
Take the 1 pink nirmatrelvir tablet and
1 white ritonavir tablet together.



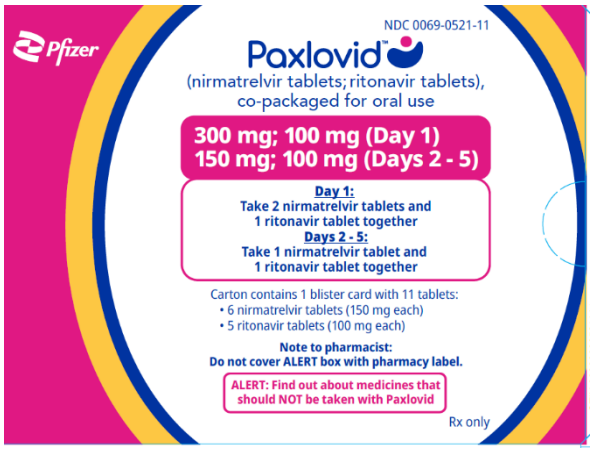


<u>Bedtime Dose:</u>
Take the 1 pink nirmatrelvir tablet and
1 white ritonavir tablet together.

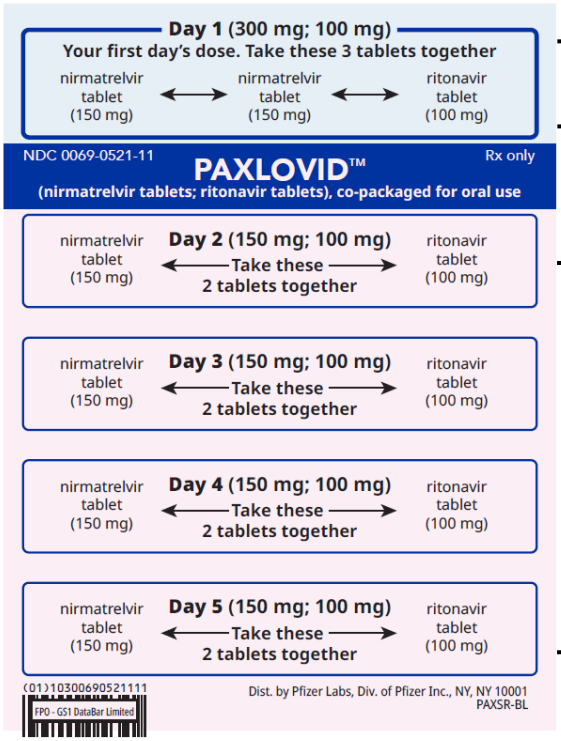


Figure C

If you are prescribed PAXLOVID 300 mg; 100 mg (Day 1) and 150 mg; 100 mg (Days 2-5)
Each dose is taken together once daily; on days of dialysis take PAXLOVID after receiving dialysis



How to take PAXLOVID 300 mg; 100 mg (Day 1) and 150 mg; 100 mg (Days 2-5)



<u>Day 1 (First Day):</u>
Take the 2 pink nirmatrelvir tablets and
1 white ritonavir tablet together
(**Blue** part of the blister card).



<u>Days 2-5:</u>
Take the 1 pink nirmatrelvir tablet and
1 white ritonavir tablet together
(**Pink** part of the blister card).



- Do not remove your PAXLOVID tablets from the blister card before you are ready to take your dose.
- If you are taking PAXLOVID tablets **twice daily** (Figure A or Figure B), take your first dose of PAXLOVID in the morning or at bedtime, depending on when you pick up your prescription, or as your healthcare provider tells you to. **Take your doses at around the same time each day.**
- If you have severe kidney disease and are taking PAXLOVID tablets **once daily** (Figure C), follow the daily dose instruction on the blister card. **Take your dose at around the same time each day.**
- 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 HIV-1 infection, 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.

What are the important possible side effects of PAXLOVID?

PAXLOVID may cause serious side effects, including:

- **Allergic reactions, including severe allergic reactions (anaphylaxis) have** happened during treatment with PAXLOVID**.** Stop taking PAXLOVID and get medical help right away if you get any of the following symptoms of an allergic reaction:
  - skin rash, hives, blisters or peeling skin
  - painful sores or ulcers in the mouth, nose, throat or genital area
  - swelling of the mouth, lips, tongue or face
  - trouble swallowing or breathing
  - throat tightness
  - hoarseness

- **Liver Problems.** Tell your healthcare provider right away if you get any of the following signs and symptoms of liver problems during treatment with PAXLOVID:
  - loss of appetite
  - yellowing of your skin and the white of eyes
  - dark-colored urine
  - pale colored stools
  - itchy skin
  - stomach-area (abdominal) pain

The most common side effects of PAXLOVID include: altered sense of taste (such as metallic, bitter taste) and diarrhea.

Other possible side effects include:
- headache
- vomiting
- abdominal pain
- nausea
- high blood pressure
- feeling generally unwell

These are not all of the possible side effects of PAXLOVID. For more information, ask your healthcare provider or pharmacist.

What other treatment choices are there?
PAXLOVID is FDA-approved for the treatment of mild-to-moderate COVID-19 in certain adults.

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.

For information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19, please go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization. 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 limited 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.

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 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).
Keep PAXLOVID and all medicines out of the reach of children.

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.

In issuing an EUA, 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 available under an EUA. The EUA for PAXLOVID is in effect for the duration of the COVID-19 declaration justifying emergency use of this product, unless the relevant EUA declaration is terminated or the EUA revoked (after which the products may no longer be used under the EUA).

What are the ingredients in PAXLOVID?

Active ingredient: nirmatrelvir and ritonavir
Nirmatrelvir inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, and sodium stearyl fumarate. Film-coating contains: hydroxy propyl methylcellulose, iron oxide red, polyethylene glycol, and titanium dioxide.
Ritonavir inactive ingredients: anhydrous dibasic calcium phosphate, colloidal silicon dioxide, copovidone, sodium stearyl fumarate, and sorbitan monolaurate. The film coating may contain: colloidal anhydrous silica, colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, polyethylene glycol, polysorbate 80, talc, and titanium dioxide.

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)

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