

Paxlovid™
(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)

If it's COVID, **PAXLOVID**

Help stop **COVID-19** from becoming severe with **PAXLOVID**: an authorized prescription treatment for mild-to-moderate **COVID-19** in people 12 years and older who are at high risk for progression to severe **COVID-19**, including hospitalization or death.



PAXLOVID is authorized for emergency use

- The Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make PAXLOVID available during the COVID-19 pandemic. PAXLOVID is not an FDA-approved medicine in the U.S. as its safety and efficacy are still being evaluated.
- PAXLOVID is an investigational medicine used to treat adults and children [12 years of age and older weighing at least 88 pounds (40 kg)] with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death.

IMPORTANT SAFETY INFORMATION

Before taking PAXLOVID, tell your healthcare provider if you:

- Have any allergies, liver or kidney disease, or any serious illness;
- Are pregnant or plan to become pregnant, or are breastfeeding a child

Please see full Important Safety Information throughout, including pages 6-7 and [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

PAXLOVID is a prescription treatment that reduces your risk of getting severely ill with **COVID-19**



PAXLOVID is authorized for:



adults and children (12 years or older and 88 pounds [40 kg] or heavier), *who*



have had mild-to-moderate COVID-19 symptoms for 5 days or fewer, and



have a high-risk factor for progression to severe COVID-19, such as being 50 years or older or having certain health conditions and/or lifestyle factors (learn more about high-risk factors on the [next page](#)).

Time matters. Be ready to take action at the first sign of COVID-19 symptoms. Fill out the **COVID-19 Preparedness Plan**, which can help you identify your high-risk factors and keep important information about your health.

Download your copy by visiting [PAXLOVIDinformation.com/plan](https://paxlovidinformation.com/plan)

PAXLOVID is not approved to prevent COVID-19, treat severe or critical COVID-19, or be used for more than 5 days. There are [certain medications that should not be taken with PAXLOVID](#).

IMPORTANT SAFETY INFORMATION (cont'd)


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.

Continued on next page.

Please see full Important Safety Information throughout, including pages 6-7 and [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

Paxlovid[™]
(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)



If you are at high risk of progression to severe **COVID-19**, don't delay

Nearly 200 million American adults have at least one risk factor that increases the likelihood that their COVID-19 will become severe. Having a high-risk factor is common, and you may have one and not even know it.

Talk to your healthcare provider to understand whether you are at high risk.

IMPORTANT SAFETY INFORMATION (cont'd)

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

- 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.

Continued on next page.

Please see full Important Safety Information throughout, including pages 6-7 and [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

If you have a high-risk factor, it's important to talk to your doctor about starting treatment as soon as possible after testing positive or if you have symptoms.

Some common high-risk factors for severe COVID-19 include:

- Being 50 years or older
- Diabetes
- Heart disease
- Smoking (past or current)
- Asthma
- Inactive lifestyle
- Being overweight or obese
- Mental health conditions (mood disorders, including depression, and schizophrenia spectrum disorders)

These aren't all the high-risk factors for severe COVID-19.

To see more risk factors and learn how PAXLOVID can help reduce your risk of getting severely ill, visit [PAXLOVIDinformation.com/who-can-take](https://paxlovidinformation.com/who-can-take)

Paxlovid™
(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)

COVID-19 may start off mild but can become severe after a few days



- Mild-to-moderate COVID-19 symptoms (such as fever, cough, sore throat, and more) can generally be treated at home
- These symptoms usually occur within the first few days of illness
- Many people get better without needing special treatment, but for some people, COVID-19 can become severe, often days into illness—this is more likely if you have a high-risk factor

If COVID-19 becomes severe, it can lead to:



Hospitalization and intensive care



Needing a ventilator to breathe



Death

PAXLOVID works to stop the virus from multiplying and reduces the amount of it in your body.

When taken within the first 5 days of mild-to-moderate symptoms, it can help keep COVID-19 from becoming severe.


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. People who are able to become pregnant should use another or an alternative effective form of contraception.

Continued on next page.

Please see full Important Safety Information throughout, including pages 6-7 and [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

Paxlovid™
(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)



In a clinical trial,
PAXLOVID helped
stop **COVID-19** from
becoming severe

A clinical trial for PAXLOVID looked at whether PAXLOVID helped prevent hospitalization or death when compared to placebo.

A total of 2246 unvaccinated adults from around the world participated in the clinical trial, all of whom had COVID-19 with mild-to-moderate symptoms for 5 days or fewer and had at least one high-risk factor for progression to severe COVID-19.*

*Based on the latest guidance, some of the high-risk inclusion criteria for the clinical trial may differ from the CDC's list of high-risk factors. PAXLOVID is authorized for emergency use in patients at high risk for severe COVID-19 as defined by the CDC.

Learn more about the PAXLOVID clinical trial at [PAXLOVIDinformation.com/about](https://paxlovidinformation.com/about)

IMPORTANT SAFETY INFORMATION (cont'd)

Take PAXLOVID exactly as your HCP tells you.

If you take too much PAXLOVID, call your HCP or go to the nearest hospital emergency room right away. If you are taking a ritonavir – or cobicistat-containing medicine for hepatitis C or Human Immunodeficiency Virus (HIV) continue to take your medicine as prescribed.

PAXLOVID reduced the risk of COVID-19–related hospitalization or death by 86%

In a clinical trial vs placebo (without active drug), **9 out of 1039** people who started treatment with PAXLOVID within 5 days of their first COVID-19 symptoms were hospitalized and none died.

For those who took a placebo, **66 out of 1046** people were hospitalized and 12 died (from any cause).

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

Continued on next page.

Please see full Important Safety Information throughout, including pages 6-7 and [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

Paxlovid™
(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)



IMPORTANT SAFETY INFORMATION (cont'd)

Do not take PAXLOVID if:

- You are allergic to nirmatrelvir, ritonavir, or any of the ingredients in PAXLOVID or are taking any of the following medicines:

- | | |
|------------------------|--|
| ◦ alfuzosin | ◦ naloxegol |
| ◦ amiodarone | ◦ phenobarbital |
| ◦ apalutamide | ◦ phenytoin |
| ◦ carbamazepine | ◦ pimozide |
| ◦ colchicine | ◦ primidone |
| ◦ dihydroergotamine | ◦ propafenone |
| ◦ dronedarone | ◦ quinidine |
| ◦ eletriptan | ◦ ranolazine |
| ◦ eplerenone | ◦ rifampin |
| ◦ ergotamine | ◦ St. John's Wort
(<i>hypericum perforatum</i>) |
| ◦ finerenone | ◦ sildenafil (Revatio®)
for pulmonary
arterial
hypertension |
| ◦ flecainide | ◦ silodosin |
| ◦ flibanserin | ◦ simvastatin |
| ◦ ivabradine | ◦ tolvaptan |
| ◦ lomitapide | ◦ triazolam |
| ◦ lovastatin | ◦ ubrogepant |
| ◦ lumacaftor/ivacaftor | ◦ voclosporin |
| ◦ lurasidone | |
| ◦ methylergonovine | |
| ◦ midazolam (oral) | |

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.

Please see additional Important Safety Information on the next page and the [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).



IMPORTANT SAFETY INFORMATION (cont'd)

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
 - hoarseness
 - throat tightness
 - skin rash
- **Liver Problems.** Tell your healthcare provider right away if you have any 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
 - diarrhea
 - high blood pressure
 - muscle aches
 - abdominal pain
 - nausea
 - feeling generally unwell

These are not all the possible side effects of 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 or call 1-800-FDA-1088, or you can report side effects to Pfizer Inc. at 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](#).

Paxlovid™
(nirmatrelvir 150 mg tablets | ritonavir 100 mg tablets)

Feeling sick? Take these steps:

- 1** Determine if you have a high-risk factor for progression to severe **COVID-19**.
- 2** Call your healthcare professional as soon as you notice symptoms—they may have you get tested.
- 3** If your healthcare professional confirms you have COVID-19, ask if **PAXLOVID** may be right for you.

Remember, PAXLOVID must be started within the first 5 days of mild-to-moderate symptoms.

For more information, visit PAXLOVIDinformation.com/prescription

EMERGENCY USE AUTHORIZATION

PAXLOVID is authorized for emergency use:

PAXLOVID has not been approved, but has been authorized for emergency use by the FDA under an EUA, for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with a current diagnosis of mild-to-moderate COVID-19 and who are at high risk for progression to severe COVID-19, including hospitalization or death; and

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. § 360bbb3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IMPORTANT SAFETY INFORMATION

Before taking PAXLOVID, tell your healthcare provider if you:

- Have any allergies, liver or kidney disease, or any serious illness;
- Are pregnant or plan to become pregnant, or are breastfeeding a child

Please see full Important Safety Information throughout, including pages 6-7 and [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#).

