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.

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. People can get COVID−19 through contact with another person who has the virus.

COVID−19 illnesses have ranged from very mild (including some with no reported symptoms) 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. 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 progression to severe COVID−19, including hospitalization or death. PAXLOVID 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

**Tell your healthcare provider about all the medicines you take,** including prescription and over−the−counter medicines, vitamins, and herbal supplements. Some medicines may interact with PAXLOVID and may cause serious side effects.
Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

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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**. Your healthcare provider can tell you if it is safe to take PAXLOVID with other medicines

**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 and ritonavir.
Take 2 pink tablets of nirmatrelvir with 1 white tablet of ritonavir by mouth 2 times each day (in the morning and in the evening) for 5 days. For each dose, take all 3 tablets at the same time.
If you have kidney disease, talk to your healthcare provider. You may need a different dose**.**
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:
 o Alfuzosin
 o Pethidine, propoxyphene
 o Ranolazine
 o Amiodarone, dronedarone, flecainide, propafenone, quinidine
 o Colchicine
 o Lurasidone, pimozide, clozapine
 o Dihydroergotamine, ergotamine, methylergonovine
 o Lovastatin, simvastatin
 o Sildenafil (Revatio®) for pulmonary arterial hypertension (PAH)
 o Triazolam, oral midazolam
 o Apalutamide
 o Carbamazepine, phenobarbital, phenytoin
 o Rifampin
 o St. John’s Wort (hypericum perforatum)

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 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:
o hives
o trouble swallowing or breathing
o swelling of the mouth, lips, or face
o throat tightness
o hoarseness
o 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:
o altered sense of taste
o diarrhea
o high blood pressure
o muscle aches

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 doctor 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 with PAXLOVID?**
Contact your healthcare provider if you have any side effects that bother you or do not go away.

Report side effects 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:/fwww.cdc.gov/COVID19. <http://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 Service (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. Toe 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 product 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.COVID19ora1Rx.com | 1 −877 −2 1 9−7225<br>(1 − 8 77 −C 19 −PACK ) |

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

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